

FDA Webinar: The Special 510(k) Program: Final Guidance

Moderator: Irene Aihie
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1:00 pm ET

Coordinator: Welcome and thank you for standing by. At this time, all participants are in a listen-only mode until the question-and-answer session of today's conference. At that time, you may press Star 1 on your phone to ask a question. I would like to inform all parties that today's conference is being recorded. If you have any objections, you may disconnect at this time. I will now turn the conference over to Irene Aihie. Thank you. You may begin.

Irene Aihie: Hello and welcome to today's FDA webinar. I am Irene Aihie of CDRH's Office of Communication and Education. On September 12, 2019, the FDA issued a final guidance document on the special 510(k) program. The new 510(k) paradigm alternate approaches to demonstrating potential equivalent and premarket notification guidance is superseded by this final guidance document and the abbreviated 510(k) program which reflects the abbreviated 510(k) information from the new 510(k) paradigm guidance.

This webinar will provide details about the final Special 510(k) Program Guidance and offer an opportunity for webinar participants to ask questions about the final guidance. Today, Angela DeMarco, 510(k) expert in the Office of Regulatory Programs and Joshua Silverstein, Regulatory Advisor in the

Office of Product Evaluation and Quality, both here in CDRH will present an overview of the final Special 510(k) Program Guidance document. Following the presentation, we will open the line for your questions related to the information provided during this presentation.

Additionally, there are other (unintelligible) subject matter experts here with us today to assist with the Q&A portion of our webinar.

Now, I give you Angela.

Joshua Silverstein: Good afternoon. Thank you for the introduction, Irene. Thank you all for joining today's webinar on the Special 510(k) Program. As Irene noted, my name is Josh Silverstein. I'm a Regulatory Advisor in the Office of Product Evaluation and Quality in the Regulation, Policy and Guidance Staff. I'll be presenting today with Angela DeMarco from the Office of Regulatory Programs, 510(k) Program. (Marjorie Shulman), Assistant Director of the Office of Regulatory Programs's Division 1 that oversees the 510(k) program, is also here to help answer questions.

The agenda for today's webinar is to explain the background on the Special 510(k) Program, the results from the Special 510(k) Program pilot, provide an overview of the special 510(k) Program including related guidance updates and resources that are available. We will then have a question and answer session.

At the end of this training, you should be able to understand the results of the Special 510(k) Program Pilot, be able to determine whether your 510(k) is appropriate to be submitted within the Special 510(k) program and prepare your 510(k) and what to expect during this review and understand how FDA updated other guidance documents to reflect the updated Special 510(k)

Program improve alignment between the related 510(k) guidance and current policies. You should also understand the resources available if you have any questions.

The Special 510(k) Program was first introduced by the guidance, “The New 510(k) Paradigm Alternative Approaches To Demonstrating Substantial Equivalence In Pre-Market Notifications.” We informally call this guidance the New 510(k) Paradigm. The New 510(k) Paradigm was issued on March 20, 1998. At that time, design controls requirements were recently introduced as part of the final rule of the Quality System Regulation under 21 CFR Part 820.

The Special 510(k) Program leverages design controls requirements and procedures along with previously submitted information that an FDA can do a summary level review for certain 510(k)s in 30 days. We would like to emphasize that the Special 510(k) Program does not alter any requirements related to 510(k) submissions or substantial equivalence including those under Section 510 and 513 of the Federal Food, Drug and Cosmetic Act and 21 CFR 807 subpart E.

In September of 2018, FDA issued draft guidance that proposed updates and clarifications to the prior Special 510(k) Program. CDRH also launched a pilot program to assess these factors. On September 13, 2019, FDA issued two separate final guidance that superseded the New 510(k) Paradigm with guidance. There's now the Special 510(k) Program and the Abbreviated 510(k) Program guidance documents respectively.

FDA also withdraw the frequently asked questions on the New 510(k) Paradigm guidance because we incorporated the information into the new

final guidance documents, or the information can be found in other FDA guidance.

Providing a new final guidance on the Special 510(k) Program is part of the Agency's ongoing effort to improve the efficiency of 510(k) Review as the FDA works to simplify this process and help promote timely access to safe effective and high-quality medical devices. The Special 510(k) Program is an optional pathway that submitters may use when they would like to introduce well-defined modifications to their own device such that design control procedures produce reliable results that can help form in addition to other 510(k) content requirements the basis of the substantial equivalent decision.

We would like to reiterate that 510(k) content requirements still apply to Special 510(k)s.

So on October 1 of 2018, CDRH launched the Special 510(k) Program pilot to allow industry and FDA staff an opportunity to test an expansion of the Special 510(k) Program. All Special 510(k)s received on or after October 1, 2018 that were marked as a special were considered as part of the pilot program to determine if they were appropriate for review as a Special 510(k). The pilot was initiated to determine whether updated eligibility factors would improve the efficiency of FDA's review of Special 510(k)s and expand the types of changes appropriate to be reviewed under this program.

So like I said already, all 510(k)s that CDRH received after October 1 of 2018 that were identified at Special 510(k) were included in this pilot. On the next two slides, we will discuss the results and the analysis reflects data captured from October 1, 2018 until July 1, 2019.

During the webinar for the Special 510(k) Program pilot, we stated that we would be collecting the following information to assess the pilot. The total number of Special 510(k)s received during the pilot if placed on hold, the FDA day on which it was placed on hold. And the total time to decision which includes both FDA and manufacturer days. If the file was found to be inappropriate to continue as a Special 510(k), we collected the reason for conversation, the day on which it was converted, and the conversation rate for the specified timeframe.

For those that do not know, FDA days are those calendar days when a submission is considered to be under review at the agency for 510(k) submission that have been accepted. For 510(k)s, FDA days begin on the date of receipt of the submission that enables the submission to be accepted. More information on these terms can be found in the MDUFA IV commitment letter on FDA's website.

The results of our data analysis from the pilot are shown on this slide. As mentioned, we analyzed data from October 1, 2018 until July 1, 2019 and compared the data to that collected during the same period during the previous calendar year. With an increase in the total number of submissions, we saw decreases in both the average total time to decision and the overall conversion rate. We believe that this is due to the new factors expanding the types of changes appropriate for review under the Special 510(k).

This also speaks to the broad range of well-established methods that allow our review staff to efficiently review the proposed changes and associated performance data. When a 510(k) during the pilot was found to be inappropriate as a special, the reason it was found inappropriate was most often that the 510(k) lacked a well-established method to assess the change

followed by the inability to place the data into a summary or risk analysis format.

Often a methodology that was either modified in such a manner that created the new method that had not been used before or the submitter had developed a new methodology in addition to using well-established methods. We would like to reiterate that all methods used within a special 510(k) should be well established to remain appropriate for review as a Special 510(k). Based on these results and comments received to the docket, we updated the final guidance to include more detail on what could be considered a well-established method. We also encourage submitters to consider presubmissions to discuss whether their proposed method is well-established if they're uncertain.

During the pilot, FDA did not automatically convert for changes to the indications for use or IFU. This was a conversation reason in the old policy and accounted for 21% of conversions. The new Special 510(k) policy focuses on the methods that are used to evaluate changes and whether any performance data can be summarized.

Occasionally 510(k)s were converted for reasons outside of the eligibility factor stated in the guidance. These were most often for clerical errors. For example, if a file was marked as a Special 510(k) but the submitter stated it was a traditional or if the file was incorrectly marked upon receipt. An additional reason is with regard to recall issues associated with the subject device.

When FDA issues the draft guidance on September 28, 2018, we requested public comment on a proposed new Special 510(k) policy. Overall we received approximately 130 comments from 13 groups or individuals which

included medical device manufacturers, trade associations, patient advocacy groups and consulting firms.

Based on comments received, we made minor changes to the guidance prior to issuing final guidance on September 13, 2019. There were three main areas that received the most comments; the eligibility factors, examples included in the guidance and clarification to the overall policy. Regarding the eligibility factors, we updated well-established methods to include those that are found in final FDA guidance documents and qualified medical device development tools or MDDTs.

The list in the final guidance is not all-inclusive. If you believe you have a method that is well-established, we encourage you to submit a presubmission to discuss the proposed method with the review team before submitting your 510(k). We also clarified that if the change involves generally more than three scientific disciplines it would not be appropriate for review as a Special 510(k). Scientific disciplines include areas such as biocompatibility, software, and electrical safety.

Most comments received on the examples were asking for more in-vitro diagnostic device or IVD examples. The final guidance includes several new IVD examples. We made minor updates to the other examples to clarify why a change was or was not found to be appropriate for a Special 510(k). General policy updates we made include a clarification that the final Special 510(k) guidance does not supersede the recommendations in other guidance documents. For example, we refer (unintelligible) to the bundling policy for how unrelated changes affect eligibility and to the reprocessed single-use devices guidance document to determine whether the change is appropriate for Special 510(k).

We also included more specificity of how to describe changes from the predicate device. For example, we encourage a tabular format with redlined copies of modified documents.

Now we will discuss differences between the new final guidance and the policy that it superseded. The Special 510(k) Program under the new 510(k) paradigm focused on whether changes affect intended use or altered the fundamental scientific technology of the device. In an internal discussion, we found that most Special 510(k) conversions under the new paradigm occurred due to methods not being within the predicate's clearance. However, there are many methods out there, including those in FDA recognized consensus standards, that are well-established such that FDA does not need to review a complete test report and would still have sufficient information to establish substantial equivalence.

FDA's updated eligibility factors in the final guidance focus on the methods used to evaluate changes that needed a 510(k). Because the program relies on existing design control processes and FDA's previous review of detailed information on the existing device, the Special 510(k) should still be submitted by the manufacturer authorized to market the existing device which in this context is also the predicate.

We'll now focus our assessment on whether any performance data is necessary, whether well-established methods exist to evaluate the change and if any data necessary to evaluate and support substantial equivalence can be reviewed in a summary or risk analysis format. We would like to reiterate that the FDA does not intend to automatically convert for changes to the indications for use.

In developing new eligibility factors, we leveraged the existing Special 510(k) Program and believed the factors in the final guidance will allow for more 510(k)s to be reviewed as specials, which was reflected in the results of the pilot which show a decrease in the conversion rate.

FDA has a flowchart in the final guidance that will be used to support decisions of whether a 510(k) can be appropriately reviewed as a Special 510(k). For the purposes of that flowchart, we assume that the manufacturer has concluded that a 510(k) is required pursuant to 21 CFR 807.81(a)(3). Additionally, this flowchart is just a visual aid and should be used with the rest of the final guidance document to determine whether a 510(k) is appropriate to be reviewed as a special. The high level process for determining whether your 510(k) is appropriate for the special pathway is outlined on the slide. The following slides will include more detail.

Starting on the left, the first step is to ensure that the device you are modifying is your own. FDA intends to convert a 510(k), Special 510(k) that's submitted for a change to a device made by another manufacturer. Next if performance data are unnecessary to support the proposed change, then the change is appropriate to proceed through the Special 510(k) pathway. If the performance data are necessary, a well-established method should be to evaluate all aspects of the change. If either of these apply to your 510(k) then we move to the next factor.

All performance data provided with the submission should be able to be summarized, reviewed in a summary or risk analysis format. The summary should be detailed enough to support substantial equivalence. If you have met all the eligibility factors then your 510(k) is most like appropriate to proceed through the Special 510(k) pathway.

I'd like to summarize the high level points again. Number 1 is that all Special 510(k)s should be submitted by the manufacturer authorized to market the existing device. Two, when performance data are not necessary that 510(k) could be reviewed as a Special 510(k). The performance data are necessary well-established methods should be available to evaluate the change. And last, the performance data should be able to be reviewed by FDS in a summary or risk analysis format without losing informant necessary to evaluate substantial equivalence.

We'll now go through each eligibility factor in a more detailed fashion. The first factor for determining appropriateness is whether the change is being made to the manufacturer's own device. This has not changed from the new 510(k) paradigm. The predicate device to which the change is being made should be the manufacturer's own device. And this is because Special 510(k) leverages the information that was already submitted to FDA and also relies on existing design control procedures developed by the manufacturer of both the predicate and the subject device.

Once it has been established that the device being modified is the predicate manufacturer's own device, we then determine whether performance data is needed to evaluate the change. We make this determination for changes to the indications for use, labeling and or technology changes.

We would like to emphasize that the FDA does not intend to automatically convert a 510(k) for changes to the indications for use. Under the final guidance we are assessing whether performance data is needed to evaluate the change before deciding to convert the submission. If performance data is deemed not necessary to evaluate the change, then the 510(k) is appropriate to continue as a special 510(k). If the performance data is deemed necessary then we proceed to the next eligibility factor.

And now Angela will discuss the remaining eligibility factors and processes for the Special 510(k) Program in more detail.

Angela DeMarco Thanks, Josh. Once it has been determined that performance data are necessary to evaluate the change, we ask whether there is a well-established method to evaluate that change. We consider well-established method to be those used in the previously cleared 510(k), methods in an FDA- recognized consensus standard or guidance document, qualified medical device development tools and methods published in the public domain that are widely available and accepted for those found acceptable in another premarket solution by the same manufacturer.

All methods identified in the subject 510(k) should be well-established. Otherwise the FDA intends to convert the submission to a traditional 510(k). If you are unsure about whether the method or methods you would like to use would be considered well-established, we encourage you to submit a pre-submission to discuss the proposed method or methods with reviewing division. It is important to note that methods that rely on clinical or animal data are typically not appropriate for the Special 510(k) Program .

If it is determined that all methods used to evaluate the change are well-established all performance data should be able to be reviewed in a summary or risk analysis format. Complete test reports should not be submitted in a Special 510(k). If complete test reports are submitted, FDA intends to determine if the data can be summarized. If FDA believes the data can be summarized, we will reach out to you so that you can place your data into a summary or risk analysis format. If FDA does not receive a timely response, we intend to convert the submission to a traditional 510(k).

If however, the data cannot be summarized because the substantial equivalence decision depends on review of the underlying data, such as images, raw graphs, or line item data, FDA intends to convert the Special 510(k) to a traditional 510(k). Please note that small numbers of representative images are acceptable as part of a Special 510(k).

There are several general instances in which a Special 510(k) may not be appropriate. If a modification to the device involve generally greater than three scientific disciplines, such as biocompatibility, electromagnetic compatibility and software, that could complicate the review such that it cannot be reasonably completed within 30 days. If a submission is bundled and the changes being made are unrelated to each other, in instances when a complete test report is necessary to establish the financial equivalence such as clinical data, novel test method, when validation method should be provided, or when a chemical characterization for toxicological assessment is needed for biocompatibility. And when validation data is required for reprocessed, single-use devices and reusable devices identified in their respective Federal Register notices.

In Appendix A of the final guidance, we provide recommendations on the content and format for Special 510(k). We encourage you to provide a detailed description of the changes you are making to the predicate device and include tabular comparison of the changes and what is remaining the same between the modified device and the cleared predicate device. If you are making modifications to document this is labeling our methodology risk analysis, we recommend including redlined copy of those documents to facilitate the review of the changes.

In addition to using the webpage on how to prepare Special 510(k), we continue to request a tabular summary of design control activities and a

summary or table that lists all changes made to the subject device compared to the predicate that is your risk analysis. When constructing your risk analysis, we recommend including a summary of verification and validation activities. This includes a summary of testing method used including deviations, the acceptance criteria and results, and other specimen of how the results support the substantial equivalence. We also expect an indication for use form and a science statement of design control activity to be provided with every Special 510(k).

The final guidance contains several examples for different types of changes and whether they would be appropriate for a Special 510(k). We will discuss three examples from that guidance over the next few slides. The example on this slide is B5 from the final guidance. It provides a labeling change to the - it involves a labeling change to the environment of use for a transcutaneous electrical nerve stimulator from a professional healthcare facility only to both a professional healthcare facility and home use. The device is still intended to be used under the direction of supervision of a healthcare professional.

It was confirmed that the predicate device is manufactured by the submitter of the Special 510(k) and that performance data are needed to evaluate the change. Electrical safety and electromagnetic compatibility testing were determined to be needed in order to assess the home use of the device because there are different acceptance criteria for home use. Both of the scientific discipline have associated FDA recognized consensus standards that can be utilized which the submitter chose to use.

In addition, the submitter tested to the FDA recognized consensus entered for home use devices. The submitter provided the acceptance criteria as a result in a summary table. The table also included a justification for all the results that were outside the bounds of the stated acceptance range or different from the

predicate so the FDA review team could adequately review the results to assess whether the device was substantially equivalent.

The results for the testing conducted could be summarized because the determination of substantial equivalent did not depend on FDA's interpretation of the underlying data such as images, raw graphs or line item data. Therefore this change can be reviewed as a Special 510(k).

This example is D3 from the final guidance. It involves a modification to the general indication for delivering elimination and laser energy for photo coagulation to include specific clinical applications for treatment of retinopathy. It was confirmed that the predicate device was manufactured by the submitter of the Special 510(k). And that performance data are needed to evaluate the change. In order to assess this change, clinical testing is typically provided in order to support the stated indication for use because the new indication identifies specific disease conditions.

The clinical output of the original submission, general coagulation of blood vessels have now become treatment of retinopathy which include decreased vision impairment. The clinical endpoints and methodology have changed from the predicate submission. And there is no consensus standard or other well-established methods available to assess the endpoint. Therefore this change cannot be reviewed as a Special 510(k).

This example is B9 from the guidance. It involves a labeling change of a blade (unintelligible) dental implant from safety and MRI not evaluated to MR conditional. It was confirmed that the predicate device is manufactured by the submitter of the Special 510(k). And that performance data are needed to evaluate the change. When manufacturers seek MR conditional labeling for device that contains a metallic component, nonclinical performance testing to

support substantial equivalent should be provided. FDA has a final guidance document that discusses the recommendations for such testing.

Because there are FDA recognized voluntary consensus standards for MR compatibility testing of passive implants, it was determined that well-established methods exist to evaluate the proposed change. However, the substantial equivalence determination relies on the review and interpretation of underlying data including device-specific pass or fail criteria and results not address in the consensus standard. This prevents the data from being appropriately summarized for review. Therefore this change cannot be reviewed in the Special 510(k). This scenario is also referenced in Section III.E of the final Special 510(k) of anticipated common scenarios for which data may be unable to be summarized.

Appendix C of the final guidance includes sample table of how to summarize design control activity. In those tables, we recommend that you include all device changes made to the predicate device and risks associated with each status change, the method or methods used to evaluate the stated changes, the acceptance criteria and any deviation made to either the method or the acceptance criteria with justification for those deviations. We ask for a justification to all deviation so that we can assess whether the method used can still be considered well-established.

We also recommend you include a summary of results that are descriptive enough to understand how results relate to the acceptance criteria and methods used. For example, for variable tests meaning tests that don't have a straightforward pass or fail criteria, you should include a description of the results such as the acceptance criteria to pass with 7 out of 10 samples. The test passed with 8 out of 10.

If you choose to leverage results from another study for test performed, for example in one of your previously cleared premarket submission, we ask that you include a justification for why that methodology and results can be leveraged for the subject device.

The process for submitting your Special 510(k) under the new final guidance has not changed. You still should identify the submission of the Special 510(k), submit a valid eCopy to the document control center and pay the user the associated with the 510(k). Please note that a hard copy duplicate of eCopy no longer is required for 510(k) submissions, but a paper copy of the cover letter is still necessary. Special 510(k)s are still subject to the RTA for refuse to accept policy and will be checked for administrative completeness. The eligibility factors as outlined in the final guidance document are on Page 1 of the Special 510(k) RTA checklist.

FDA still intends to process Special 510(k) within 30 days. We anticipate the review to be interactive meaning requests for additional information will be made through email. However, the option for a hold to request additional information still exists for complex issues.

If the 510(k) is found to be inappropriate to continue via the Special 510(k) pathway, FDA intends to convert it to a traditional 510(k). The process for converting the 510(k) remains the same as under the prior policy. The lead reviewer obtains (unintelligible) and then seeks 510(k) staff concurrence. If converted, the lead reviewer will notify the official contact and explain the reason for the conversion. If converted, this may delay the review process because FDA will likely request complete test reports.

In addition to splitting the new 510(k) paradigm guidance into this Special 510(k) Program guidance and the abbreviated 510(k) guidance, we issued two

other related final guidance. The refuse to accept, or RTA guidance, was updated to reflect the new Special 510(k) policy, improve alignment between related 510(k) guidance and to reflect current policies such as those found in the final guidance content of premarket submissions from management of cybersecurity and medical devices and final guidance “Use Of International Standard Iso 10993-1 Biological Evaluation Of Medical Devices: Part 1 Evaluation And Testing Within A Risk Management Process.”

We also updated the “Format For Traditional And Abbreviated Premarket Notifications” guidance to align with the order of the RTA checklist and include current guidance and website links. You may have noticed that Sections 10 and 11, device description and executive summary respectively have switched positions in the final guidance compared to the prior version. This was only done to align with the RTA checklist. The updates made to this guidance are not intended to reflect new policy.

All four documents of the Special 510(k) Program, the Abbreviated 510(k), RTA and Format guidance were issued as final guidance on September 13, 2019. Due to the need for FDA and industry to have time to operationalize changes made to the RTA guidance, there's a 60-day delayed implementation in effect for the RTA guidance. This means that if a 510(k) is received before or up to 60 days after the publication date, FDA may decide not to refuse to accept based on the criteria in the new final guidance.

The implementation date for RTA will be November 13, 2019. This holds true for Special 510(k) RTA decisions as well. FDA will determine whether a submission is appropriate to proceed as a Special 510(k) using the eligibility factors as described in the new final guidance but intends to use the prior RTA guidance document to determine whether a file is administratively complete and accepted for substantive review.

Here are the links to all four final guidance documents should you have additional questions following this webinar.

Thank you for your attention. This concludes the presentation. We are now happy to take questions.

Coordinator: Thank you. We will now begin the question and answer session. If you would like to ask a question, please press Star 1. Unmute your phone and record your name. Your name is required to introduce your question. This does take a few moments for the question to come through. Please continue.

Angela DeMarco While we wait for the first question, we do have some frequently asked questions that we wanted to share. The first one is, is the Special 510(k) limited to specific product codes? And the answer is assuming that the changes are appropriate to be reviewed as a Special 510(k), there is no restriction on product codes for the Special 510(k) Program.

Joshua Silverstein: Another frequently asked question that we have tried to reiterate through this webinar is can I submit a Special 510(k) if I've changed the indications for use? Yes, but the submission should rely on well-established methods and any data that's necessary should be able to be summarized in a risk analysis format.

Angela DeMarco: Operator, we'll take our first question.

Coordinator: Thank you. And it does come from (Meghan Parker). Your line is open.

(Meghan Parker): Hi, thank you for the presentation. I have a question on the change in the program regarding intended use and indications for use. As you mentioned

earlier, the guidance discusses the differences between the previous program in which Special 510(k)s that included modifications to indications for use or any labeling change that affected the device's intended use were routinely converted to traditional 510(k)s. And under this new program, FDA now no longer intends to focus on changes that affect indications for use in determining whether a 510(k) is appropriate as a Special 510(k).

Given that change in focus, under the new program, will FDA routinely convert Special 510(k)s that seek an OTC indication for a device previously cleared as a prescription to traditional? Or could a 510(k) or Special 510(k) be appropriate for a prescription to OTC switch if the submission otherwise meets the standards in the new guidance?

Angela DeMarco Thank you for the question. We do in general consider a change from prescription to over-the-counter to be a change to indication for use. However, we do not intend to automatically convert for that type of change. It would depend on the type of performance data need, if any, to make this change. And if the performance data could be handled in a - through a well-established method and placed into a summary or risk analysis format, then it could proceed as a Special 510(k). But it does depend on whether or not the performance data necessary to support it could be done through a well-established method.

(Meghan Parker): Okay, thank you.

Coordinator: The next question comes from (Steven Inglesi). Your line is open.

(Steven Inglesi): Yes, good afternoon and thank you for taking my call and thank you for the presentation. We are a consulting firm that offers small business regulatory and quality support. On the regulatory side, we are often doing letters to file

based on looking at the FDA guidance when to submit or change - do a submission for a change device. We're constantly doing letters to file because we find that, and the client finds that to be appropriate. At what point would you see a Special would have to be done to - for the agency to recognize all the minor changes a firm has made to their medical device?

Joshua Silverstein: So this guidance would apply once the manufacturer has already made an assessment that a 510(k) is required.

(Steven Inglesi): Okay. And so - if not, then we'd just be continuing to do letters to file because we find that appropriate based on guidance. So I thank you for your thoughts on that.

Joshua Silverstein: Thank you.

Coordinator: The next question comes from (Chris). Your line is open.

(Chris): Yes, hi. I'm focusing on software in medical devices and software as medical devices. And I'm still trying to get my - wrap my head around the performance data and the requirements or the guidance around that. So if a software change entailed using new or modified test protocols and by that I mean new or modified from the original submission or the predicate device, would that fact alone mean that a Special 510(k) is inappropriate? Or not?

Angela DeMarco Thank you for the question. So if you're making modifications to the software test protocols, we do encourage you to submit redlined copies so that the FDA review team can see exactly what changes are being made to help them determine whether or not it could still be considered a well-established method. If you do have concerns, you could submit a presubmission prior to the 510(k) to obtain feedback from the FDA review team.

(Chris): Okay, thank you.

Coordinator: The next questions comes from (Cliff Frederick). Your line is open.

(Cliff Frederick): Thank you for the opportunity to ask this question to you. If the holder of the original 510(k) changes their device by adding a component where that component has a previously 510(k) cleared change or technique that is held by another company, can the safety and performance testing methods referenced in the other company's 510(k) would qualify as a well-established method? I mean the same test methods would apply to the Special 510(k) device.

Joshua Silverstein: It would depend. If that was an internal protocol that other manufacturer that information would be protected from disclosure by FDA. If it was a method that was well-established in the public domain whether it be FDA-recognized standards, an MDDT or something that like, that would be appropriate. But in terms of sort of like tapping into someone else's confidential information that something that we're not permitted to do.

(Cliff Frederick): No, if they have a signed agreement between those two companies.

Joshua Silverstein: If there is a signed agreement, that might be through a master file or through something else, that's something would probably - you would probably want to discuss that specifically with the review division, but if you had authorization from that party then that sounds like (unintelligible) okay.

(Cliff Frederick): Right, so can that authorization be included in the administrative section as an appendix to the cover letter can be (unintelligible) submission?

Joshua Silverstein: Yes.

(Cliff Frederick): Okay, thank you so much for answering my question.

Coordinator: The next question comes from (Marisa). Your line is open.

(Marisa): Hello. So earlier the first presenter, the gentleman mentioned that not all of the 510(k) contents apply to the Special 510(k) content. And I was wondering if you could provide a list of which ones are not applicable?

Joshua Silverstein: I'm sorry if I misspoke. What I meant to say was that all content requirements do apply to a Special 510(k). I'll just refer you to Appendix A of the guidance of the final guidance document and that's your roadmap for the recommended content of a Special 510(k).

(Marisa): I guess are 510(k) summaries and truthful and accuracy statements also applicable for a Special 510(k) like they would be a 510(k) because I didn't see that explicitly called out in that appendix.

Joshua Silverstein: Yes.

(Marisa): Okay great, thank you so much.

Joshua Silverstein: Thank you.

Coordinator: The next question comes from (Jean Asquith). Your line is open.

(Jean Asquith): Hi, yes. I'm calling in order to - I need to know if to submit a Special 510(k) both design verification and validation as well as process validation has to be completed before actually submitting the 510(k).

Angela DeMarco Yes, we do expect that all performance testing be completed prior to the submission of the 510(k).

(Jean Asquith): Okay, thank you.

Coordinator: And as a reminder, it is Star 1 if you would like to ask a question. The next question comes from (David Chadwick). Your line is open.

(David Chadwick): Yes, I wanted to ask. I just don't recall if a 510(k) filed under the S&P program is eligible for special or not. And if not, why not?

Angela DeMarco So once we have eligible devices under the safety and performance pathway, nothing would explicitly prohibit it from being a special 510(k) unless it does not meet the eligibility factors as stated in the guidance.

(David Chadwick): Okay, so under S&P though it would follow all established accepted methods, wouldn't it? Sorry for the follow-on?

Joshua Silverstein: Sorry, could you repeat that?

(David Chadwick): Under an S&P guidance that FDA issues wouldn't that include use of established methodology? So it wouldn't be a reason for rejection or conversion? And it should be applicable to a special if it's your own device.

Angela DeMarco Yes, as long as it does meet those well-established criteria and is able to be appropriately summarized or placed into a risk analysis format such that substantial equivalence could be determined from that summary format, then yes it could be appropriate for a Special 510(k).

(David Chadwick): Okay, thank you.

Coordinator: And the next question comes from (Alyssa). Your line is open.

(Alyssa): Yes, hello, hi. Thank you for the presentation. I wanted to ask - you mentioned that there were three - you mentioned, I guess, biocompatibility and sterilization let's say. Because I have, let's say I have a submission that I have those two changes and of course their established methods. The question is, is that sufficient for a Special 510(k)?

Angela DeMarco Do you mean that if you were only to submit the biocompatibility and sterilization?

(Alyssa): Yes, I mean those are the two main changes that - for this specific device.

Coordinator: And are you ready for the next question?

Angela DeMarco One second (unintelligible).

Coordinator: Okay, thank you.

Angela DeMarco Answer the previous question.

((Crosstalk))

(Alyssa): Did you understand my question?

Angela DeMarco Yes, we do understand it now. If it is under the three different scientific disciplines it is mostly likely appropriate for the Special 510(k) program. If it was more than ...

(Alyssa): So what you're saying is if it was only two let's say ...

Angela DeMarco (Unintelligible). I'm sorry. Go ahead.

(Alyssa): Yes, I'm sorry. I didn't understand. You said if it's under three, so if I said it's only biocompatibility and sterilization, so that's - would that be eligible for a Special 510(k)?

Joshua Silverstein: Provided that you're able to - that Number 1, they're well-established methods to evaluate the change. And that the data can be summarized, yes.

(Alyssa): Okay.

Angela DeMarco We'll take our next question.

(Alyssa): Okay, thanks.

Coordinator: Okay, thank you. That comes from (Suder). Your line is open.

(Suder): Hi, so my question has to do with the three scientific disciplines as well. I was just curious if cybersecurity would qualify as a discipline? And as a follow-up I also wondered if there's additional thoughts that you have shared on the topic of cybersecurity beyond that example that's mentioned for wireless testing.

Joshua Silverstein: In general, we consider cybersecurity to be under the umbrella of software. In terms of additional thoughts on cybersecurity, unfortunately that's outside of the scope of today's webinar.

(Suder): Thank you.

Coordinator: The next question comes from (Caperon). Your line is open.

(Caperon): Good afternoon. I was wondering if there's a list of what the FDA considers scientific disciplines that they're going to decide if what the threshold is.

Angela DeMarco We currently don't have a special list of what we consider to be separate scientific disciplines, but if you do have any concerns, we do recommend reaching out to the review team.

(Caperon): Thank you.

Joshua Silverstein: If any 510(k) were submitted or excuse me were converted for this reason, we would explain what those disciplines are in the conversion notification.

Coordinator: The next question comes from (Miya). Your line is open.

(Miya): Hey, thank you. My question was also related to a scientific discipline. One of my questions there are a few more. Is a human factor that you would consider as a scientific discipline?

Angela DeMarco Yes, we would consider human factors to be a scientific discipline because it does have its own set of testing.

(Miya): Okay and I just saw a slide. I was - I'm not sure what was on it, but it was about when it's not appropriate and it was stated something was human factor and (unintelligible). I have a project that does exactly that because our change is related to usability user needs. And so we, what we have to do is do a new (unintelligible) because we're talking about a small diameter with the same method as before, but we have to revalidate it anyway. And we have to do a

revalidation of the handling due to this change. And I would like to know if it's still appropriate for a Special 510(k) if we have to do this.

Joshua Silverstein: So you have a very device-specific question and we do recommend reaching out to the reviewing division. But just to kind of take a step back, there are situations where human factors validation data may not be able to be reviewed in a Special 510(k), but that doesn't mean that a human factors evaluation cannot be reviewed in a Special 510(k). Oftentimes, that just relates to how much information is going to be necessary to establish substantial equivalence.

(Miya): Okay, so it's not necessary just because there is a change and that requires human factor thing does not require. Okay, that's all I want to know. Thank you.

Joshua Silverstein: Thank you.

Coordinator: Thank you, and as a reminder, please limit your questions to one question in order to allow everyone to ask their questions today. Up next is (Jeffrey Wan). Your line is open.

(Jeffrey Wan): Hi and thank you for the presentation. I have a question regarding the submission of reusable devices that are reprocessed. I understand that all reprocessing data needs to be provided as complete test reports as per the federal register notice. However, in the situation where there is a proposed change that could affect the reprocessing, but the company intends to leverage results from a previous submission and not provide any additional reprocessing data, would this change still disqualify from Special 510(k) eligibility?

Joshua Silverstein: So if you were able to explain why no new validation data would be required in the 510(k), then it would be eligible for Special and we do have that on Page 14 of the guidance. I mean I'd refer you to that bullet. It's the last sentence.

Coordinator: Thank you, and the next question comes from (Chris). Your line is open.

(Chris): Yes, hi. Actually this is a follow-up question to my previous question about software in which you indicated that new or modified software test protocols should be submitted in a redlined version for the FDA to evaluate. The question, the follow-up question that I have is should the detailed test results also be included in the Special 510(k) submission.

Angela DeMarco So in a special 510(k) we do anticipate that all results would be in a summary or risk analysis format rather than the complete test results if you do feel the need to submit your complete test results, the Special 510(k) may not be appropriate. But this is something that you can discuss with the review team as to whether or not your results could be appropriately summarized.

Coordinator: Thank you. And the next question comes from (Melissa Summerfield). Your line is open.

(Melissa Summerfield): Yes, so my question has to do with timing for Special 510(k)s. With the 30 days being the target for review for a Special 510(k), when additional information is requested, does the clock stop until the information is received? And with the goal to still stay within 30 days?

Angela DeMarco Yes, one the file is placed on hold, you receive a hold letter. The FDA clock is paused until we receive your response. And FDA does still intend to complete the review within a total of 30 FDA days.

(Melissa Summerfield): So if that hasn't happened, should we contact the reviewer?

Angela DeMarco You can reach out to the review team. You can also reach out to the 510(k) program staff in case the time does go well over the 30 days. You can reach out to us with any questions about that.

(Melissa Summerfield): Thank you very much.

Coordinator: Up next is (Robert Molinaro). Your line is open.

(Robert Molinaro): Hello. The presentation said that a Special 510(k) is not appropriate if validation data should be provided. I wanted to know when is it necessary to provide validation data.

Joshua Silverstein: So there are circumstances where it is a requirement and so for example we have two Federal Register notices that one of the previous questions related to on reusable devices and also reprocessed single-use devices.

Coordinator: And you're ready for the next question?

Joshua Silverstein: Yes, please.

Coordinator: Thank you. That comes from (Repala). Your line is open.

(Repala): Hi, everyone. Good presentation, FDA. So my question is regarding a device which has two components. One is a catheter and one is electrical (unintelligible). So the change in the device would be two have the same catheter but replace the user interface which is an electrical complement to the (unintelligible) complement which is already cleared and manufactured by the

same company. So the testing would be doing majorly to have the compatibility between these two complements. So my question is that this change qualifies for a Special 510(k) and the second is that if we - if it qualifies and we have a predicate device, which one to be the primary predicate or can we use more than one predicate to justify? Because they are two complements part of the device.

Angela DeMarco So to generalize the issue, because it is somewhat device-specific, we typically expect that the device being modified serves as the primary predicate to the subject device within the Special 510(k). If you do have concerns about which device would be your predicate device, we do recommend you reach out in the presubmission to discuss how you would format your submission in terms of identifying the predicate device and how to explain the modifications made if you do have questions about that.

Coordinator: The next question comes from (Jackie Burinski). Your line is open.

(Jackie Burinski): I have a question regarding the conversion rate and the specific criteria for conversion from a Special to a traditional. So among the 25% in the pilot period that were converted, 59% were converted for well-established methods. Could you provide any additional information around what some of those well-established methods (unintelligible) during that pilot period?

Angela DeMarco Specifically if it was converted for lack of a well-established method, oftentimes it could have been novel clinical data that was provided, novel animal data as we have stated in the guidance. Those are typically not appropriate for a Special 510(k). There are other instances in which modifications to a well-established method were made such that it would no longer be considered to be a well-established method. If you do intend on modifying a consistent standard for example in order to fit your specific

device and are unsure whether or not it could still be considered a well-established method, we do recommend reaching out to the review team to discuss the changes to see whether or not it could still be considered a well-established method.

Coordinator: Thank you. And the next question comes from (Purnell). (Purnell), your line is open. Your line is open (Purnell). Would you like me to move on?

Angela DeMarco Yes, please.

Coordinator: The next question comes from (Mary). Your line is open. Hello, (Mary) your line is open.

Angela DeMarco We'll take the next question.

Coordinator: Thank you and that comes from (Azita). Your line is open.

(Azita): Yes, hello. You mentioned that the changes can be submitted in a risk analysis format. Is there any specific format that the FDA has in mind or you can point us to?

Joshua Silverstein: Absolutely, we have example formats in Appendix C of the guidance document.

Coordinator: The next question comes from (Jean Asquith). Your line is open.

(Jean Asquith): Hi, I was just wondering. Does the FDA require all actions related to user validation be completed prior to submitting a Special 510(k) or can the Special 510(k) be submitted once all bench verification is completed and substantially equivalence is established knowing the design controls will

require all user and process validations as required will be completed prior to launch?

Angela DeMarco The FDA does expect all validation and performance data be completed prior to submitted the 510(k) so that we can make an appropriate determination to substantial equivalence.

Coordinator: The next question comes from (Chrissy Jakemar). Your line is open.
(Chrissy Jakemar), your line is open.

(Shrudi): Is that for (Shrudi)?

Coordinator: Go ahead, your line is open.

(Shrudi): Hi, can you hear?

Coordinator: Yes, go ahead.

(Shrudi): Hi, what options are there for manufacturers when they disagree with the conversion?

Angela DeMarco If you disagree with the conversion as stated in the notification that the lead reviewer will send you, you can reach out to the lead reviewer and request further clarification. If you do have additional questions, please feel free to reach out to the 510(k) program staff and we would be happy to discuss the policy issue with you to ensure that both sides understand the policy and the conversion.

Coordinator: The next question comes from (Jackie Ban). Your line is open.

(Jackie Ban): Hey, sorry I have a question about the timelines. I know you mentioned it's going to be 30 days even if the file is put on hold. I know with traditional 510(k)s, there's the 60 days before the (SI) deadline and then it can be placed on hold. Is there an (SI) deadline for the Special 510(k), say at Day 15? Or it's just whenever FDA chooses to put the file on hold, they can, and then the clock resumes?

Joshua Silverstein: I'm sorry.

Angela DeMarco I'm sorry. For Special 510(k) we don't have an official (SI) date. We do encourage that lead reviewers if they do need to put it on hold, put it on hold approximately 20 days into the FDA review cycle. But there is no official (SI) date.

Coordinator: The next question comes from (Joan Berdstrum). Your line is open. (Joan Berdstrum), your line is open for your question.

(Joan Berdstrum): Hello, thank you. Can you hear me now?

Joshua Silverstein: Yes.

Coordinator: Yes, go ahead.

(John Berdstrum): Perfect. Thank you for the detailed webinar. I appreciate the information. My question is around indications for use. Can you direct me to resources to be able to identify whether an indication for use would be considered under this Special 510(k)?

Joshua Silverstein: So what we're trying to get both industry and our staff away from is even the discussion of indications for use in the context of whether a 510(k) is

appropriate. You would just typically - you would go through the flowchart and the accompanying text in the guidance document. And not think about indications for use in terms of whether your 510(k) is appropriate to be reviewed as a Special.

Coordinator: And as a reminder, it is Star 1 if you would like to ask a question. Please limit your questions to just one in order to allow everyone to ask their questions. And I do have the next question coming from (Purnell). Your line is open.

(Purnell): All right, thank you. Let's try this again. My name is (Purnell) and I have a question regarding the summary formats part of the decision tree and one of the examples or a couple of the examples in the guidance was talking about the manufacturer being able to provide the data in a summary format. Yet it was deemed not appropriate for a Special 510(k) because the FDA needed to review the underlying data to establish (unintelligible) equivalent decision. So my question is, I was wondering if the FDA is intending to provide additional guidelines as to situations where the FDA needed to review such underlying data or whether data can be summarized in acceptable summary format.

Joshua Silverstein: We do give two or three different examples throughout the guidance document. And so one of them includes the review of images. And so for certain data images might be captures using benchtop performance testing. And a few representative images and we're talking more in the radiology space are typically provided along with a board-certified radiologist. But if FDA believes that it needs to review a full dataset of images for a 510(k), we don't think it would be appropriate for review.

Another example are graphs and so this might come up in certain testing methodologies for magnetic resonance compatibility. And do if the FDA

believes that we needed to review those graphs to establish substantial equivalence, that's another circumstance where data cannot be summarized.

Coordinator: The next question comes from (Don Peters). Your line is open.

(Don Peters): Hi, this is in regard to some of the questions with regard to multiple software changes and letter to files. If a Special 510(k) is needed, your suggestion is to bring redlines especially to change protocols. I was wondering if you could comment on how to best address that for incremental changes versus changes in aggregate. Thank you.

Angela DeMarco If you do make changes to the software protocol or methodology, we do ask that if applicable, use the redlined copy when you submit to the FDA. If it is a broader change to the software structure and you're uncertain whether or not this change could be appropriate for a special, we do recommend that you reach out to the review team to determine the extent of the change and whether or not it would be appropriate for a Special 510(k).

Coordinator: Thank you. And the next question comes from (Alyssa).

(Alyssa): Yes, hello again. My question is I have a 510(k) that I'm planning to submit. And actually it's based on two 510(k)s. Again, these two 510(k)s were for legal devices that were cleared by the same manufacturer. I just wanted to know if I can submit this submission as a special based on those two 510(k)s.

Joshua Silverstein: Provided that you are able to get through the flowchart with one predicate. It sounds like it would be okay. But it would definitely depend on the individual circumstances of the submission.

Coordinator: And the next question comes from (Elaine).

(Elaine): Hi, my question is, is it considered intended use if some (unintelligible) are removed from (unintelligible)?

Joshua Silverstein: I'm sorry. Could you please repeat the question?

(Elaine): Yes, my question is, is it considered intended use if some warnings (unintelligible) are removed?

Joshua Silverstein: So if warnings are removed from the instructions for use?

(Elaine): Right.

Joshua Silverstein: Yes, I mean so I think that's outside the scope of the guidance that we're talking about today. That relates more to our modifications policy. Did you have a question about how it relates to appropriateness in the Special 510(k) Program?

(Elaine): No, thank you.

Joshua Silverstein: Okay.

Coordinator: And there are no other questions at this time. I'll turn it back to Irene Aihie. Thank you.

Irene Aihie: Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questions. Today's presentation and transcript will remain available on the CDRH learn webpage at www.fda.gov/training/cdhrlearn by Friday, November 8. If you have additional questions about today's

presentation, please use the contact information provided at the end of the slide presentation.

As always, we appreciate your feedback. Following the conclusion of today's live webinar, please complete a short 13-question survey about your FDA CDRH webinar experience. This survey can be found www.fda.gov/cdhrwebinar immediately following the conclusion of today's live webinar.

Again, thank you for participating. This concludes today's webinar.

Coordinator: That does conclude today's conference. Thank you for participating. You may disconnect at this time. Speakers allow a moment of silence and stand by for your post-conference.

END