FDA Webinar: Safety and Performance Based Pathway Performance Criteria

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 of today's conference. At that time to ask a question, press Star 1 on your phone and record your name at the prompt.

Today's call is being recorded. If you have any objections, you may disconnect at this time.

I would now like to turn the call over to Irene Aihie. Ma'am, 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 19, 2019, the FDA issued four draft guidances and updated a final guidance related to the safety and performance-based pathway as part of our commitment to strengthening and modernizing the 510(k) program as described in the FDA's medical device safety action plan.

Today's webinar will provide details about the draft guidances and offer an opportunity for webinar participants to ask questions about the draft

guidances. Today Jason Ryans, technical guidance specialist in the Office of Product Evaluation and Quality here in CDRH will present an overview of the pathway including the updated final guidance and the draft guidance documents.

Following the presentation we will open the line for your questions related to the information provided during the presentation. Additionally, there are other center subject matter experts here with us today to assist with the Q&A portion of our webinar.

Now, I give you (Jason).

Jason Ryans: Thank you, Irene and good afternoon to everyone joining us. Today's webinar will provide an overview of the safety and performance-based pathway established in final guidance earlier this year as well as an introduction to the recently issued accompanying device-specific draft guidances.

The agenda for today's webinar includes a review of the objective for today's presentation, some background information on the safety and performance-based pathway, an overview of the safety and performance-based pathway final guidance issued earlier this year, an introduction of the four draft device-specific guidances issued this past September, some general information about 510(k) submissions to the new pathway, a brief look at FDA's future plans for the pathway and potential opportunities for stakeholder engagement.

The objectives for this presentation are to walk through the policy of the safety and performance-based pathway as well as provide a brief overview of how the device-specific guidances will be utilized to submit a 510(k) submission once they are finalized.

You may remember that in April 2018, the FDA released its medical device safety action plan. This described recent actions we've taken to enhance device safety and outlined our vision for how the agency can build on these initiatives to further ensure the safety and effectiveness of medical devices. In this plan, we committed to continue modernizing our approach to device safety. As part of our commitment in November 2018, former FDA Commissioner Dr. Scott Gottlieb and CDRH Director Dr. Jeff Shuren issued a joint statement announcing some of the steps the FDA is taking to modernize its 510(k) pathway.

The 510(k) program has undergone numerous changes since its inception through the medical device amendments of 1976. Over time, FDA has evolved the program as the statutory requirements progressed and the medical device technological landscape advanced. These changes were implemented in an effort to ensure that the public would have timely access to safe and effective medical devices.

Previously, the special and abbreviated 510(k) pathways were developed through guidance to create an efficient submission preparation and review process, while still promote FDA's mission to protect the public health. In particular the abbreviated pathway established a reliance on guidance documents, special controls and/or voluntary consensus standards to facilitate FDA's pre-market review of 510(k) submissions. While also -- without altering the statutory requirements for substantial equivalence. It is this basis that the FDA leverages to establish the safety and performance-based pathway.

The purpose of this pathway is to establish a voluntary more modern 510(k) pathway for demonstration of safety and effectiveness for certain well-understood devices. To facilitate a more modern paradigm, FDA intends to

expand the existing 510(k) program to allow manufacturers of certain well-understood device types to use objective performance criteria established or recognized by the agency to demonstrate substantial equivalence.

FDA will ensure that the objective criteria represent performance that is equivalent to modern technology. This approach will provide more direct evidence of the safety and performance of a device and better information for patients and providers to make well-informed healthcare decisions. Additionally, it will provide an opportunity for device developers to demonstrate that their product meets or exceeds these modern performance criteria as well as the ability to do so and in a more straightforward and streamlined manner.

The framework for this voluntary pathway was first outlined in draft guidance released in April 2018. Finalized in February of this year and then updated this past September. As mentioned previously the safety and performance-based pathway is optional and will not impede the use of other 510(k) pathways including the traditional, special and abbreviated. Submitters will demonstrate that a new device meets FDA-identified performance criteria to demonstrate that the device is as safe and effective as a legally marketed device.

Importantly, if a legally marketed device performs at certain levels relevant to its safety and effectiveness, and a new device meets those levels of performance for the same characteristics, FDA can find that the new device is as safe and effective as a legally marketed device. Instead of reviewing data from direct comparison testing between the two devices, FDA can support a finding a substantial equivalence based on data showing the new device meets the level of performance of an appropriate predicate device.

As a side note, device types that are eligible for third-party review in addition to being appropriate for the safety and performance-based pathway, will remain eligible for the 510(k) third-party review program.

As part of this pathway, FDA will identify appropriate device types and performance criteria through guidance that will undergo a public comment period before finalization. This will give an opportunity for stakeholders to provide input on the FDA-identified criteria and methods. It is important to note that FDA will show that these criteria will represent performance levels that are at least equivalent to the performance of already legally marketed devices of the type to which they apply.

Performance expectations described in a safety and performance device-specific guidance can come from a variety of sources. This includes FDA-recognized consensus standards, other FDA guidance, special controls, scientific literature and historical 510(k) submission data. In some cases these performance criteria may be described qualitatively such as some testing for biocompatibility.

Additionally, performance criteria that are in FDA-recognized consensus standards but not identified explicitly in a safety and performance device-specific guidance should not be used in this pathway. FDA will ensure that the identified criteria are applicable to the device types explicitly described in the scope of each device-specific guidance.

Once a device-specific guidance is finalized and the pathway can be implemented, new submissions will be evaluated through the same 510(k) substantial equivalence decision flowchart as before. However, this pathway is unique in that to demonstrate performance, the subject device should meet all of the FDA identified criteria in the device-specific safety and performance

guidance. Importantly, FDA believes these criteria are appropriate to determine substantial equivalence when the indications for use and technological characteristics do not raise different questions of safety and effectiveness from that of a predicate device. And that the criteria align with one or more predicates of the same device type.

Similar to other 510(k) pathways, an appropriate predicate should be identified for this pathway to determine that the new device's indications and technological characteristics do not raise new questions of safety and effectiveness. The subject device should be within the scope of the device-specific guidance to ensure that the performance criteria appropriately align with the anticipated performance of the proposed device.

The amount and type of information necessary to support a finding of substantial equivalence under this pathway are summarized in the following table. And can also be found in Table 1 of the safety and performance-based pathway final guidance. To support an FDA finding of substantial equivalence through this pathway, FDA expects the submitter to demonstrate that the new devices meets the FDA identified criteria by submitting either a declaration of conformity to an FDA recognized consensus standard, a testing protocol, a result summary, and/or a complete test report as appropriate.

For example, from the table provided, when a device-specific guidance identifies a performance test where the methodology comes from an FDA-recognized consensus standard, and the criteria are FDA established for instance from analysis of historical 510(k) submissions, then the submitter can provide a declaration of conformity to the standard and a result summary for FDA to make a determination of substantial equivalence.

Importantly, while a submitter may use an alternative to an FDA recommended test methodology accompanied with a complete test report, the FDA identified criteria should still be met. In some instances, submission information may deviate from this table slightly depending on the particular information that is used to satisfy the FDA identified criteria. Nevertheless, the device-specific guidances will outline what the expected submission information should be for each performance test.

For the purposes of this pathway and to ensure that the performance criteria remains contemporary and take into account relevant data from recent clearances, FDA recommends that you provide a result summary for all tests evaluated in addition to other submission information, for example, a declaration of conformity, identified for each test or evaluation in the device-specified guidance.

Consistent with FDA policy for all 510(k) submissions, FDA may request and review underlying data demonstrating that a new device meets the FDA identified performance criteria and testing methodology as necessary. If data provided by the submitter do not show that the new device meets the performance criteria FDA has identified for the device type, then FDA would not be able to find that the new device is a substantially equivalent through this pathway.

As previously mentioned, submitters could still use other available 510(k) pathways to demonstrate substantial equivalence. For additional information on the use of declarations of conformity and information regarding the submission of nonclinical bench testing information, please see the FDA guidance as referenced at the bottom of this slide.

In September of this year, FDA issued the first four device-specific draft guidances that outline the FDA-identified performance criteria and test methods for device types appropriate for the pathway once they are finalized. The device types include cutaneous electrodes for recording purposes, conventional Foley catheters, spinal plating systems, and orthopedic non-spinal metallic bone screws and washers. For each device-specific guidance, when possible FDA will prioritize the inclusion of performance criteria and methodologies from FDA-recognized consensus standards. Otherwise, FDA intends to leverage the knowledge, experience, and applicable data within the agency to establish appropriate criteria and methods.

As mentioned previously, some criteria may be qualitative and FDA will make an effort to not deviate from current practices, excuse me, to assess these evaluations. To identify which device types are appropriate for the pathway, FDA will include information and the scope of each device-specific guidance such as the regulation, product code, device characteristics, intended use, and/or indications for use.

Additionally, FDA-identified devices may be a subset of a particular regulation and/or product code. To ensure a least burdensome assessment of certain evaluations, many crosscutting recommendations such as biocompatibility and sterility will be assessed consistent with current practices and crosscutting guidances.

For ease of accessibility, FDA will make available any and all device types and their accompanying device-specific guidances on the safety and performance-based pathway webpage. This website will also contain any supplemental information to assist in the submission of 510(k)s to the pathway. Once device-specific guidances are finalized, FDA intends to periodically review the appropriateness of device types for inclusion in the

pathway based on a number of factors. This may include an evolution in the scientific understanding of the safety and/or effectiveness of a device, or the emergence of a particular safety signals after marketing of the device.

FDA reserves the right to add or remove device types appropriate for the pathway and may revise performance criteria or test methodologies over time as necessary. The decision to modify or remove a device type for the pathway will be based on the ability to support a determination of substantial equivalence, particularly if it is deemed that the current performance criteria are not adequate to fully address the safety and effectiveness of a device.

Importantly, any changes made to the list of device types that can use the pathway would be applied prospectively to devices from which a 510(k) has not yet been submitted. Therefore a 510(k) that is cleared for a device type that is later removed from the pathway would still be considered a legally marketed device. However, any future submissions should be submitted through either the traditional, special or abbreviated pathway.

I would now like to highlight a few things to consider when submitting a 510(k) to the safety and performance-based pathway once it is finalized. This is not an exhaustive list and may be subject to changes as we get closer to the finalization of the device-specific guidances. As with other premarket applications, the Pre-submission process is available if further clarification is needed to determine if your device is appropriate for the pathway as well as the appropriateness of test methods outside of those recommended by FDA.

Additionally, the Pre-submission can be used to determine on a case-by-case basis if additional testing you identify outside of the guidance is necessary to demonstrate the safety and performance of the device. For instance, if you'd

like to add language to your labeling concerning magnetic resonance compatibility, then additional performance testing would be necessary.

The refuse to accept process, or RTA, will be consistent with the refuse to accept policy guidance and will be similar to that of the abbreviated RTA checklist. Similar to the traditional and abbreviated pathways, the safety and performance-based pathway will have an FDA review clock of 90 days and the timeframe for the RTA and substantive interaction will also be the same.

Moving forward, FDA's next priority will be to fully implement the safety and performance-based pathway. Currently, the four device-specific draft guidances are open for public comment and we encourage all stakeholders to participate in providing feedback. Once the comment period has closed, we will review the comments and make any necessary changes to issue a finalized version. Additionally, FDA will continue to develop device-specific draft guidances for the pathway and anticipates continued issuance in the near future.

As always, FDA encourages stakeholder interaction to facilitate the development of key policy initiatives. Particularly for the safety and performance-based pathway, there are a number of ways stakeholders can contribute. This includes identifying device types that may be potential candidates for inclusion into the pathway, identifying standardized criteria and scientific methods applicable to appropriate device types, and ways to better harmonize with other regulatory jurisdictions.

Again, we encourage all stakeholders to submit comments to the individual dockets for the device-specific guidances which will be open until December 19 of this year. Additionally, the docket for the safety and performance-based

pathway final guidance is and will remain open to receive general comments about the pathway.

Listed here are a number of links to items concerning the safety and performance-based pathway that can be accessed once the slides are published on FDA's website.

And with that, I would like to thank you for your time and will now open the phone lines for questions.

Coordinator: Thank you. We'll now begin the question and answer session. If you would like to ask a question, please press Star 1 on your touchtone phone. Make sure your phone is unmuted and record your name clearly when prompted. Your name will be required to introduce your question. If you need to withdraw your question, you may press Star 2. Again, to ask a question, please press Star 1 and record your name. It will take a moment for questions to come through. Please stand by.

Jason Ryans: While we're preparing for the question and answer session, I'd like to reiterate a couple of important points. One, the current draft device-specific guidances will be open for comment until December 19 and we highly encourage all stakeholder input. Second, the safety and performance-based pathway cannot be implemented until the current device-specific draft guidances are finalized which will occur sometime next year.

Coordinator: And I'm showing no questions in the queue at this time. But again if you would like to ask a question, please press Star 1 and record your name.

And we do have a question coming in. One moment. And our question comes from (Robert Phillips). Your line is now open.

(Robert Phillips): Thank you and thank you for the presentation today. My question is, do you have any idea when we may see additional guidances for additional products? And if you don't have a list you're already working on, is there a way for industry to submit products that we would be interested to see safety and performance guidelines on?

Jason Ryans: Yes, so we are continually working on draft guidances for different product areas. And we will be issuing some draft - additional draft guidances in the near future. If you wish to submit some suggestions as I mentioned, the safety and performance final guidance docket is a place where you can submit any product areas as well as standardized criteria or potential methodology that we can evaluate.

(Robert Phillips): Very good, thank you.

Coordinator: And again, if you'd like to ask a question, please press Star 1 and record your name. Please stand by. I'm showing no further questions in the queue at this time. And so I will turn the call back over to Irene Aihie.

Irene Aihie: Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questions. Today's presentation and transcript will be made available on the CDRH learn webpage at www.fda.gov/training/cdrhlearn by Friday, November 15. 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-questions survey about your FDA, CDRH webinar experience. This survey can be found at

www.fda.gov/cdrhwebinar immediately following the conclusion of today's live webinar.

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

Coordinator: That concludes today's conference. Thank you for participating. You may disconnect at this time.

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