

510(k) Third Party Review Program Overview

Welcome to the 510(k) Third Party Overview. I'm Greg Pishko in FDA's Center for Devices and Radiological Health and I'm the Program Lead for the 510(k) Third Party Review Program. Under this program, Third Party Review Organizations perform FDA-equivalent reviews of 510(k) submissions for eligible lower-risk devices. In this Overview, I'll give some background about the Third-Party Review Program and its benefits, then talk about one enhancement to the Program - that is, device-specific training modules posted on CDRH Learn.

Let's start with some background. The Third-Party Review Program is a voluntary alternative review process. It allows an accredited Third-Party Review Organization, or Third Parties for short, to conduct a review of a 510(k) instead of FDA. This benefits FDA and the public health. FDA can focus more resources toward the review of high-risk and complex devices, while still maintaining confidence that lower risk, less complex devices reviewed by Third Parties are safe and effective. Ultimately, new medical products can reach the market and U.S. patients faster.

There are two key pieces to the Third-Party Review Program, first, the Accreditation of Third Parties, and second, the 510(k) reviews themselves. The first piece of the program, Accreditation, is how FDA ensures that Third Parties can perform FDA-equivalent reviews of eligible devices. Accreditation helps FDA and the public be confident in the recommendations that Third Parties make.

Once accredited by FDA, Third Parties may perform the second piece of the program - the 510(k) reviews themselves. In the Third-Party Program, 510(k) applicants may choose to send their 510(k) submission to a Third Party instead of to FDA. The Third Party forwards the completed review and recommendation, along with the original 510(k) submission, to FDA.

By law, FDA must issue a final decision within 30 days after receiving the recommendation of a Third Party. An effective and efficient review by a Third Party, along with FDA's 30-day deadline, shortens the entire 510(k) review process and helps devices get to market faster.

Now let me talk about an improvement to the Third-Party Program - that is, giving Third Parties the information they need to make FDA-equivalent reviews.

In 2017's Medical Device User Fee Amendments to the FDA Reauthorization Act, also known as MDUFA IV, FDA was charged with eliminating routine FDA re-review of 510(k)s already reviewed by Third Parties. As a result, we developed Third Party device-specific training videos for CDRH Learn. These videos give Third Parties the information to perform an FDA-equivalent review of eligible 510(k) submissions, tailored to specific device areas.

In each video, an FDA subject matter expert walks through the full review process for a specific device type and includes examples to illustrate key points. We created these CDRH Learn modules to help Third Parties understand the 510(k) review process and expectations. A high-quality Third Party review helps to eliminate the need for FDA to conduct routine re-review of Third Party submissions. We hope you find this CDRH Learn series helpful. Thanks for watching.
