

**FDA Webinar: Safety and Performance Based Pathway
Criteria for Certain Device Types Final Guidances**

**Moderator: Irene Aihie
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1:00 pm ET**

Coordinator: Welcome and thank you for standing by. At this time all participants will be on a listen-only mode until the question-and-answer session of today's conference. To ask a question from the phone lines please press star 1 and record your name at the prompt. Objections, please disconnect at this time.

Irene Aihie: Thank you. Hello. And welcome to today's FDA webinar. I am Irene Aihie of CDRH's Office of Communications and Education. On August 13, 2020, the FDA issued two final guidance documents providing performance criteria for specific device types in support of the safety and performance-based pathway.

As part of our commitment to strengthening and modernizing the 510(k) program, the FDA announced in February 2019, the framework for this voluntary safety and performance-based pathway through final guidance. These guidance's allow for implementation of the safety and performance-based pathway and provide an alternative 510(k) pathway for certain Class 2 moderate risk devices to gain clearance for marketing, by demonstrating that they meet modern performance criteria identified by the FDA.

Today, Jason Ryans, Technical Guidance Specialist in the Office of Product Evaluation and Quality here in CDRH, will present his overview of the final guidance documents. He is joined by other center subject matter experts to assist with the Q&A portion of this webinar. Following the presentation, we will open the line for your questions related to information provided during the presentation.

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 device-specific performance criteria final guidances that were issued in August of this year. This will allow the first device types to be submitted to the safety and performance-based pathway. Additionally, we will discuss some of the aspects related to submitting a 510(k) to this pathway. Next slide, please.

The agenda for today's webinar includes a review of the objectives for today's presentation, some background information on the safety and performance-based pathway, a walkthrough of the different sections of the device-specific performance criteria final guidance, a discussion about what should be considered when submitting a 510(k) to the safety and performance-based pathway, a brief look at FDA's future plans for the pathway, and potential opportunities for stakeholder engagement. Next slide, please.

The objectives for this presentation are to walk through a device-specific performance criteria final guidance, and discuss how these guidances should be used for this pathway. This talk will also go over aspects of submitting a 510(k) to the safety and performance-based pathway, also called the S&P pathway. Next slide, please.

First, I would like to go over some of the progress that we've made in establishing the safety and performance-based pathway. In February 2019 FDA issued the safety and performance-based pathway final guidance. This acted as a programmatic guidance for the pathway and outlined the general framework and policies of the pathway.

In September 2019 we issued the first four device-specific performance criteria draft guidances. A listing of the device-specific guidances can be found on FDA's Web page for the safety and performance-based pathway that is included in the references at the end of this presentation. These guidances outline the methods and criteria that should be met to submit a 510(k) to this pathway.

It is important to note that draft guidances are not for implementation and cannot be utilized for this pathway until the final version is issued. In November of 2019 a webinar was presented outlining the general framework and policies of the pathway. I would encourage you, those of you looking for additional information, regarding the programmatic guidance, to check out that webinar.

In December 2019 and February 2020 we issued additional device-specific performance criteria draft guidance for magnetic resonance coils and soft daily wear contact lenses. Then recently in August, we issued the first two device-specific performance criteria final guidances, which include conventional Foley catheters and cutaneous electrodes for recording purposes. Again, with these two final guidances issued, it is now possible to submit a 510(k) to the pathway for these particular device types. Next slide, please.

The purpose of this pathway is to establish a voluntary, more modern 510(k) pathway to demonstrate the safety and effectiveness for certain well-

understood devices. To facilitate a more modern paradigm, FDA expands upon the abbreviated 510(k) pathway to allow manufacturers of certain well-understood device types to use objective performance criteria established or recognized by the agency to demonstrate substantial equivalence.

Importantly, 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. In this new pathway 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. Overall, the goal is to facilitate an approach that would provide more direct evidence of the safety and effectiveness of a device in a more straightforward and streamlined manner. Next slide, please.

To identify which device types are appropriate for the pathway, FDA will include information in 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 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.

These crosscutting recommendations will also be identified in each device-specific performance criteria guidance as they are applicable. I would also like to emphasize again that only device-specific performance criteria guidances, in their final form, can be implemented in the pathway. That means any devices within a device-specific guidance that is in draft form going through the public commenting period, cannot be used to submit a

510(k) to the S&P pathway, but could still use the other available 510(k) pathways.

The device-specific performance criteria guidances that are currently able to be used to submit a 510(k) to the S&P pathway, are for conventional Foley catheters and cutaneous electrodes for recording purposes. Next slide, please. As part of this pathway, FDA will identify appropriate test methods and performance criteria through guidance that will undergo a public commenting period before finalization.

This will give an opportunity for stakeholders to provide input on the FDA-identified criteria and methods. FDA would ensure that the objective performance criteria represents performance that is at least equivalent to the performance of legally marketed devices. Importantly, if a legally marketed device performs at a certain level relative to its safety and effectiveness and a new device meets those same levels of performance for the same characteristics, then FDA could find that the new device is as safe and effective as the legally marketed device.

Instead of reviewing data from direct comparison testing between the two devices, the FDA could support a finding of substantial equivalence based on data showing that the new device meets the level of performance of an appropriate predicate device. Next slide, please.

Performance expectations described in a S&P device-specific guidance can come from a variety of sources. This can include 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 do not identify explicitly in a device-specific safety and performance guidance should not be used for 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. Next slide, please. Now I would like to walk through one of the device-specific performance criteria final guidances recently issued, to discuss how the information within should be used when submitting a 510(k) to the S&P pathway. In this example we will be looking at sections pulled directly from the conventional Foley catheter's performance criteria guidance.

This will cover the characteristics of Foley catheters that are appropriate for the pathway, an example of a performance test with the relevant information that should be submitted to meet the performance criteria, and an example of a crosscutting recommendation that should be included as part of a submission to the pathway. Next slide, please.

First, we will look at the scope and device description of Foley catheters appropriate for the S&P pathway. As you can see in the top paragraph, the appropriate device type is identified by the regulation number, in this case 21 CFR 876.5130, and the product code, EZL. It is important to note that this particular guidance should only be used for devices with that particular regulation and product code.

The second section outlines the intended use and indications for use of eligible Foley catheters. For instance, as part of this guidance, eligible devices would be those that are single use and have indwelling times of 30 days or less. This is based on FDA's assessment that the performance testing and criteria established in the guidance, adequately addresses the current level of performance of legally marketed devices.

Lastly, the bottom section outlines the design characteristics of Foley catheters that are eligible for the S&P pathway. In this case, the guidance described the range of French sizes and the maximum balloon volume of Foley catheters that should be evaluated. Additionally, this device-specific guidance will outline characteristics that FDA believes are outside the scope of submission to the pathway.

For Foley catheters you can see this includes three lumen catheters, catheters with lubricious coatings, suprapubic catheters and antimicrobial catheters. Please note that this list of exclusionary characteristics may not be exhaustive but FDA will do its best to provide a comprehensive listing of what we believe to be appropriate. If you have questions about whether or not your device is appropriate for the pathway, then we would encourage you to reach out via a Q-Sub. Next slide, please.

We will now look at an example performance test to be evaluated when submitting a 510(k) to the S&P pathway for Foley catheters. As a reminder, all performance criteria in a device-specific performance criteria guidance, should be met to submit a 510(k) to this pathway. This particular performance test assesses the Foley catheter flow rate as described in the FDA-recognized consensus standard, ASTM F623.

Each performance test in all of the device-specific performance criteria guidances will follow a similar format to what is seen here. This includes the test name, the recommended test method, performance criteria, the source of the performance criteria and the type of information to be submitted to effectively show that the performance criteria were met.

Additionally, some performance tests may have additional considerations that FDA think are important to communicate to the manufacturer. Importantly, the amount and type of information that is provided for each test will be consistent with the policies outlined in table 1 of the safety and performance-based pathway programmatic guidance. In the case of this test, the submission information would consist of a declaration of conformity to ASTM F623.

For additional information about declarations of conformity, I would encourage you to read FDA's guidance, *Appropriate Use of Voluntary Consensus Standard and Pre-Market Submissions for Medical Devices* which can also be found in the reference slide. 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. Next slide, please.

The last topic I'd like to discuss for this device-specific example, is a crosscutting recommendation that would be part of your 510(k) submission, in this case a biocompatibility evaluation. In this particular recommendation, we have outlined the biocompatibility endpoints that should be assessed specific to Foley catheters, described in the scope of this guidance. This is based on the categorized contact type and contact durations that are also described in this section.

Importantly, these endpoints match that of Attachment A in the CDRH biocompatibility guidance. Any other applicable crosscutting recommendations, for instance, electrical safety or sterility, will be outlined in each device-specific performance criteria guidance and will be consistent with any FDA guidance on that specific topic. Next slide, please.

Now let's switch gears and discuss some of the nuances to submitting a 510(k) to the S&P pathway, the first of which is determining whether your device is appropriate for the pathway. As I mentioned previously, the scope of each device-specific performance criteria guidance will identify which device types are appropriate and that you should satisfy. You should also meet all of the performance criteria outlined in the device-specific guidance.

Additionally, although it is not necessary to conduct side by side performance testing of a subject device to a predicate, it will still be necessary to identify an appropriate predicate for your submission, as you would in any other 510(k) pathway. Next slide, please.

I would now like to highlight a few key points - oh, I'm sorry. When submitting a device-specific guidance for the S&P pathway, 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 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. Next slide, please.

Now I would like to highlight a few key points to consider when submitting a 510(k) to the safety and performance-based pathway. Similar to the traditional and abbreviated pathways, the safety and performance-based pathway will have a MDUFA review clock of 90 days. Additionally, the MDUFA user fees will be the same as any other 510(k). When submitting a 510(k) submission

we are asking that manufacturers identify that their submission is intended for the S&P pathway in the submission cover letter. This will help FDA adequately process the submission in our system. Next slide, please.

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 510(k) RTA checklist. Timeframes for the RTA and substantive interaction will also be the same. As with other 510(k) pathways, there will be an opportunity for a 510(k) submitted to the S&P pathway to be converted if there are issues that preclude review through this pathway.

Ideally, determination of whether or not a 510(k) is appropriate for the pathway will be made during the RTA review stage at which point conversion to another pathway would be appropriate. If it is determined after the RTA review stage, that their submission does not meet the criteria or has insufficient information as outlined in a device-specific performance criteria guidance, then there will still be an opportunity for conversion to another pathway. However, the conversion of a submission to another viable 510(k) pathway may necessitate additional testing with a predicate comparison. Next slide, please.

As with other pre-market submissions, the pre-submission or Q-Sub process is available if further clarification is needed to determine if your device is appropriate for the pathway. This can also be used to determine the appropriateness of test methods outside of those recommended by FDA, to meet the identified performance criteria. Additionally, a Q-Sub 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 wanted to add language to your labeling concerning magnetic resonance compatibility and there as not performance testing in the device-specific guidance for this feature, then additional performance testing would be necessary. Next slide, please.

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; it could be identifying standardized criteria and scientific methods applicable to particular device types; it could also include ways to better harmonize with other regulatory jurisdictions.

Again, we encourage all stakeholders to submit comments to the device-specific performance criteria draft guidances during the public commenting period, as they are issued in the future. Additionally, the docket for the safety and performance programmatic guidance linked on the slide, will remain open to receive suggestions about the pathway and is monitored regularly. Next slide, please.

And listed here are a number of links to items concerning the safety and performance-based pathway to be accessed once the slides are published on FDA's Web site. Next slide, please. And we can move onto the final slide. And with that, I would like to thank you for your time and we will now open the phone line for questions.

Coordinator: Thank you. We will now begin the question and answer session. To ask a question from the phone lines please press star 1, ensure your phone is unmuted and record your name at the prompt. Your name is required to

introduce your question. To withdraw your question, press star 2. One moment please, for incoming questions.

Jason Ryans: And so while we're preparing for the question and answer session, I'd like to address a couple of common questions that we've received recently, the first being can you propose device-specific topics to be added to the safety and performance device list? And the answer to that is yes. As I just mentioned recently, the safety and performance programmatic guidance docket is still open and recently people have submitted numerous topics that FDA is reviewing on a continual basis.

Coordinator: Once again, as a reminder, to ask a question from the phone lines, please press star 1 and record your name at the prompt. At this time there are no questions from the phone lines.

Irene Aihie: Thank you. Jason, would you want to have - do you have any closing remarks before we end the call?

Jason Ryans: I think the main thing I would say is if you're looking for more information about the safety and performance-based pathway, we do have a FDA Web page dedicated particularly to this pathway, which you can find in the resource slides of this presentation. And it outlines all of the device-specific guidances that are in draft and final form currently. And we will be updating that Web page as more device specific guidances come forward.

Irene Aihie: Thanks so much, Jason. Again, this is Irene Aihie. And we do appreciate your participation today. Today's presentation and transcript will be made available on the CDRH Learn Web page at www.FDA.gov/Training/CDRHLearn, by Friday, October 2. 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 do appreciate your feedback.

Following the conclusion of today's webinar, please complete a short 13 question survey about your FDA CDRH webinar experience. The survey can be found at www.FDA.gov/CDRHWebinar, immediately following the conclusion of today's live webinar. Again, thank you for participating and this concludes today's webinar.

Coordinator: Thank you all for your participation in today's conference. You may now disconnect. Speakers please hold for post-conference.

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