

FDA Webinar: Special 510(k) Program Pilot

Moderator: Irene Aihie
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Coordinator: Welcome and thank you for standing by. All participants will be in listen-only mode until the question-and-answer session. At that time please press Star followed by the number 1 to ask a question.

Today's conference is being recorded. If you have any objections, you may disconnect at this time. I'd now like to turn the call over to your host, Irene Aihie. 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 October 1, the FDA launched the Special 510(k) program pilot which aims to expand on the types of changes eligible for the program to include the efficiency of the 510(k) review.

The program pilot allows the FDA and industry (with respect to expansion) with a Special 510(k) program. The goal of the program pilot is to determine whether updated factors for eligibility in the Special 510(k) program will help improve the FDA staff efficiencies in reviewing 510(k) submissions.

Today Joshua Silverstein, Regulatory Advisor and Angela DeMarco, Biomedical Engineer in the Office of Device Evaluation here in CDRH will present an overview of the Special 510(k) program pilot. 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 to assist with the Q&A portion of our Webinar. Now I give you Josh and Angela.

Joshua Silverstein: Good afternoon. Thank you for the introduction, Irene and thank you all for joining today's Webinar on the Special 510(k) program pilot. As Irene noted, my name is Joshua Silverstein. I'm a Regulatory Advisor in the Office of Device Evaluation. I'll be presenting today with Angela DeMarco from the Office of Device Evaluation's 510(k) staff.

Marjorie Shulman, Director of the 510(k) staff, is also here to help answer questions. The agenda for today's Webinar is to understand the purpose of the Special 510(k) program pilot, background on the Special 510(k) program, differences between the program pilot and the existing program and effects on the current review of Special 510(k)s.

At the end of this training, you should be able to determine whether your 510(k) is appropriate to be submitted within the Special 510(k) program pilot with consideration of the updated eligibility factors. We will also discuss what to expect from the review process during the pilot.

The purpose of this pilot is to determine whether updated factors for eligibility in the Special 510(k) program will improve FDA staff's efficiency in reviewing 510(k) submissions.

The Special 510(k) program was first introduced by the FDA guidance document *The New 510(k) Paradigm: Alternative Approaches to Demonstrating Substantial Equivalence in Premarket Notifications*, which was issued on March 20th, 1998.

At that time, design controls requirements were recently introduced as part of the final rule for the Quality System Regulation. In summary, the Special 510(k) program leverages design controls requirements and procedures along with previously-submitted information so that 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 sections 510 and 513 of the Federal Food, Drug and Cosmetic Act and 21 CFR 807 Subpart E.

FDA periodically pilots different programs. Most recently such pilots have been in the 510(k) program to help improve consistency and efficiency along with reduced total time to decision. Total time to decision is the number of calendar days from the date of receipt of an accepted or filed submission to a MDUFA decision.

Our MDUFA for shared outcome goal for total time to decision for 510(k) submissions will decrease to 108 days by Fiscal Year 2022. To achieve this goal, updating the Special 510(k) program was identified by CDRH as a means to reduce total time to decision without sacrificing the quality of FDA's review standard.

This is because FDA intends to process Special 510(k)s in 30 days rather than the 90 days required by section 510(n)(1) of the Federal Food, Drug and Cosmetic Act.

All 510(k)s that CDRH receives on or after October 1st, 2018 that are identified as a Special 510(k) will be included in the pilot to determine whether they're appropriate to be reviewed in the Special 510(k) Program Pilot.

However, we would like to note that 510(k) submissions that are reviewed by the Center for Biologics Evaluation and Research or CBER are not included in the Special 510(k) Program Pilot. Now we will discuss differences between the pilot and the existing program.

In developing new eligibility factors, we've leveraged the existing Special 510(k) program and believe that the pilot's factors will allow for more 510(k)s to be reviewed as a Special. With that being said, we believe that submissions that could have been submitted under the existing program are still eligible and appropriate to be reviewed in the Special 510(k) Program Pilot.

Because the program relies on existing design controls processes and FDA's previous review of detailed information regarding 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 device.

The Existing special 510(k) program focuses on whether or not the changes affect intended use or alter the fundamental scientific technology. In internal discussions we have found that most Special 510(k) conversions occur 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 in all situations so one can see now that FDA's updated eligibility factors focus on the methods used to evaluate the changes that needed a 510(k).

We will now focus our assessment on whether any performance data is necessary but 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.

FDA also has a flow chart that will be used to support determinations of whether a 510(k) can be appropriately reviewed as a Special 510(k) in this pilot. We'd just like to note that we assume that the manufacturer has made an assessment that a 510(k) is required per 21 CFR 807.81(a)(3).

Additionally, this flow chart is just a visual aid and should be used with the rest of this presentation to determine whether a 510(k) is appropriate to be reviewed as a Special. Angela will soon discuss the explanatory text for Special 510(k) eligibility but we'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. Number 2, when performance data are not necessary, that 510(k) could be reviewed as a Special. If performance data are necessary, well-established methods should be available to evaluate the change.

Number 3 that performance data should be able to be reviewed by FDA in a summary or risk analysis format without losing information necessary to

evaluate substantial equivalence. Now Angela will discuss the eligibility factors and processes for the Special 510(k) Program Pilot in more detail.

Angela DeMarco: Thanks, Josh. The first eligibility factor for determining whether a Special 510(k) is appropriate to proceed through the Special pilot is whether the change is being made to the manufacturer's own device. This has not changed from the existing Special 510(k) policy.

The predicate device to which the change is being made should be the manufacturer's own device. This is because a Special 510(k) leverages the information that was already submitted to the FDA and relies upon existing design controls procedures developed by the manufacturer of both the predicate and subject device.

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

This differs from the existing policy in that most changes to the IFU would trigger a conversion to a Traditional 510(k). Under the pilot program, we are assessing whether testing is needed to evaluate the change before deciding to convert the submission. If testing is deemed not necessary to evaluate the change, then the 510(k) is appropriate to continue as a Special 510(k).

If testing is deemed necessary, then we'll proceed to the next eligibility factor. Once it has been determined that testing is necessary to evaluate the change, the question of whether there is a well-established method to evaluate the changes is asked.

We consider well-established methods to be those used in the previously cleared 510(k), methods in an FDA-recognized consensus standard or guidance document, and methods published in the public domain that are widely-available and accepted, or those found acceptable in another premarket submission 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 it is determined that the methods used to evaluate the change are well-established, all data should be able to be reviewed in a summary or risk analysis format. This has not changed from the existing Special 510(k) policy.

Full test reports should not be submitted in a Special 510(k). If full 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 involves several different scientific disciplines such as biocompatibility, electromagnetic compatibility, and software, that could unduly 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; instances when a complete test report is necessary to establish substantial equivalence such as clinical data, novel test methods; and when validation data should be provided and when validation is data is required for reprocessed single-use devices and reusable devices identified in Federal Register notices.

The way you prepare your 510(k) for this Special 510(k) pilot has not changed from the existing recommendations for preparing a Special 510(k). In addition to using the FDA guidance, Frequently Asked Questions on the New 510(k) Paradigm and the Webpage on How to Prepare a 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.

We recommend that, if appropriate and possible, you include redlined copies of modified documents. The process for submitting your Special 510(k) under the pilot is the same as the current method for submitting a Special 510(k). You still need to identify the submission as a Special 510(k), submit a valid eCopy to the Document Control Center and pay the user fee associated with the 510(k).

Please note that a hard copy duplicate of the eCopy is no longer required but a paper copy of the cover letter is still necessary. The only change to the review process under the pilot program is that the RTA checklist created for the pilot program contains the pilot eligibility factors on Page 1 rather than the eligibility factors for the existing program.

No changes to the rest of the RTA checklist were made. All RTA items for Special 510(k)s remain the same as under the existing policy. FDA still intends to process Special 510(k)s within 30 days.

We anticipate the review to be interactive, meaning requests for additional information will be made through e-mail. 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 this Special 510(k) pathway, FDA intends to convert it to a Traditional.

The process for converting the 510(k) remains the same as under the existing program, meaning the lead reviewer obtains his or her management concurrence and then seeks 510(k) Staff concurrence. If converted the lead reviewer will e-mail the official contact and state the reason for the conversion.

To assess the pilot, we will be collecting the number of Special 510(k) submissions received, the 510(k) number for tracking, the FDA Day it was placed on hold, if applicable, and the Total Time to Decision and if the submission was found inappropriate to proceed as Special 510(k), we will collect the reason the FDA Day on which it was converted and the total number of submissions that were converted.

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) submissions that has been accepted. For 510(k)s the FDA Days begin on the day of receipt of the submission that enables a submission to be accepted.

More information on terminology on this slide can be found in the MDUFA IV commitment letter on FDA's Webpage. This pilot began on October 1st,

2018. All 510(k)s received on or after October 1st and that are marked as the Special 510(k) will be considered as part of the pilot program to determine if they are eligible. There is no additional designation needed.

We believe that there are several benefits to this pilot. Namely, it expands the types of changes eligible for the Special 510(k) program, it will improve the efficiency of review and decrease the total time to decision and promote timely access to safe, effective and high-quality medical devices.

Here are some additional resources 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 and at this time to ask your question, please press star then 1. Please unmute your phone and record your name clearly at the prompt. To withdraw your request, please press star 2. Once again please press star 1 at this time to ask a question. One moment, please, for the first question.

Angela DeMarco: While we're waiting for the first question to be queued-up, a frequently-asked question that we have been receiving is whether or not the Special 510(k) pilot program is limited to specific product codes. The answer to this is no. Assuming the changes are appropriate to be reviewed as a Special 510(k) there is no restriction on product codes.

Coordinator: And for our first question, it comes from (Elizabeth Orr). Your line is open.

(Elizabeth Orr): Hi, thanks for taking my call. I was wondering do you have a benchmark for how long the pilot will run or how many devices you plan to accept?

Angela DeMarco: So, we intend to run this pilot for as long as we need to collect information to appropriately assess the pilot's success. As to the second part of your question, there is no limit on the types of products. It's determined on whether or not the change that you are making to your product is appropriate for the Special 510(k) pathway.

(Elizabeth Orr): Okay, thank you.

Coordinator: Next question from (Paige Gridick). Your line is open.

(Paige Gridick): Hi, thank you. You mentioned if there is a numerous or difficult changes and inside of that you mentioned things like novel sterilization and software. If you have a software-only medical device and you're making changes to that, does that automatically make it ineligible for the new pilot program?

Joshua Silverstein: Hi, thanks for your question. Provided that the software change uses a well-established method for verification of validation and it can be summarized, it can be presented in Special 510(k) so that particular aspect of software and Specials hasn't really changed from the existing programs to the pilot. Typically what we would see in a special 510(k) are redlined versions to what was previously submitted in the last 510(k).

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

(Karen Jaffe): Yes, hi. We had written confirmation from the agency on a Special 510(k). On Day 28 we received a hold letter, responded to that and then on Day 73 received a conversion to a traditional and we did not receive any rationale for that. I was wanting to know is if a part of this pilot you are going to assess the time at which the conversion to a traditional is going to be assessed as well?

Angela DeMarco: Yes, as part of this pilot we will be assessing if the file is converted we will be tracking the FDA Day that was actually placed on hold or converted so we will be tracking both of those elements.

(Karen Jaffe): Okay.

Coordinator: The next question is from (Mike Dockerty). Your line is open, sir.

(Mike Dockerty): Yes, hi, thanks so my question is if we want to add supplemental technical information to a product that to the indications for use and to the IFU instructions for use for a product that is already released, does that fall into the Special 510(k) pilot?

Joshua Silverstein: Could you be a little bit more specific about what you're discussing?

(Mike Dockerty): So if we are so we have infusion systems, right, and if we want to include as part of our instructions for use, the flow rates that one can expect from the infusion system for various combinations of the accessories, would that fall - if we wanted to add that to our instructions for use - would that fall into the classification for this Special 510(k) pilot?

Joshua Silverstein: Yes, so that's a very device-specific question but the best advice that I could offer you is after you've determined that you need a 510(k) whether you need one, you would then look at whether or not those methods are well-established.

So assuming that you had already submitted that kind of information under your previous 510(k) to the agency, you know, including such labeling information seems reasonable but I would definitely recommend reaching-out to the reviewing division.

(Mike Dockerty): Okay, thank you.

Coordinator: Next question from (Sakra Shabal), your line is open.

(Sakra Shabal): Hello, can you hear me?

Angela DeMarco: Yes, we can hear you.

(Sakra Shabal): Okay, good, for those products that are allowed to use third-party reviewers, can those third-party reviewers do Special 510(k) reviews or do these go directly to the FDA?

Angela DeMarco: Third-party reviewers can submit Special 510(k)s as long as they are, you know, an accredited third-party review group, they can submit the Special 510(k) under this pilot program.

(Sakra Shabal): Okay, thanks you.

Coordinator: Next question from (Timothy Cole), your line is open.

(Timothy Cole): Thank you. I'd like to know regarding changes to your medical device but this is based on a prior device that you manufacture, how many changes are permissible on this special 510(k)? Is it only like one change if it has to do - affects - the function of it but everything else is the same so it won't be converted to a traditional or ...

Joshua Silverstein: So we're not restricting the program to just one change but that being said, we don't think that it's feasible for the agency to do a complete re-review of a

device in 30 days and so there is a little bit of a threshold where a certain number of changes trips the need for us to convert to a Traditional 510(k).

(Timothy Cole): Okay, could you clarify for example whereas can you cite an example?

Joshua Silverstein: So for example a change involving multiple review disciplines like a simple material change that contacts patients would often involve some kind of biocompatibility assessment and potentially mechanical testing or other kinds of performance data that are outside the biocompatibility evaluation. We do think that that is well within the Special 510(k) program.

I think it's more if you're introducing let's say a mains powered unit to a previously-unpowered product, you're changing patient-contacting materials that also affect the performance of the device. That kind of gets into a situation where we don't think that we can feasibly review those particular devices in 30 days.

(Timothy Cole): Okay, so we have a good chance if there's only one change versus more than one change and keeping our special 510(k) submission?

Joshua Silverstein: Correct.

(Timothy Cole): All right, thank you.

Coordinator: Next question from (Anthony Moss), your line is open.

(Anthony Moss): Hello, thank you guys for hosting this. This has been very informative so I was looking through some of the exclusions that you have from these 510(k) Specials list from earlier in the meeting and I was wondering if I could just dive into one of them as an example.

So if a company's submitting a 510(k) with testing methods and results for say MR compatibility, can that same company submit a special 510(k) using the same testing methods for different products as a special?

Angela DeMarco: A different product meaning a different manufacturer's product or a different product made by the same manufacturer?

(Anthony Moss): Different products from the same manufacturer using the same test methods.

Joshua Silverstein: So I think what you would want to lay out in that particular submission is why you think those methods are still well-established even though it's a different product. Just in general, we think that initial MR conditional labeling is very difficult for the agency to review outside of the traditional 510(k).

Once those methods are put into place which often involve device-specific considerations, we do think that we can review certain minor changes to say, you know, material dimensions or etcetera, within a Special so it really would boil-down to the specifics of the change and how different those two products are from one another.

(Anthony Moss): Okay, cool, thank you, I really appreciate that.

Coordinator: Next question is from (Justin Traver), your line is open.

(Justin Traver): Yes, thank you for holding this today. Fortunately my question was answered a few questions prior to this about to how many changes is appropriate to submit our special 510(k).

But in addition maybe we can ask one more question regarding that is what if for example if you have a small design change that might only result in some functional testing let's say and in order to submit under the 510(k), you're going to want to meet latest guidances on like cleaning and sterilizations for example?

Joshua Silverstein: Are these considered, would this put you over the threshold for the number of changes acceptable under the special 510(k) if my question makes sense so I guess it would depend on the particular device. Like for example if your device was in Appendix E of the reprocessing guidance, I think that we would likely scope that out of the Special program.

If they were sort of like a non-critical reused device that could be potentially eligible within a Special but I think it's really hard to give you a good answer without knowing the specifics of your device.

(Justin Traver): Yes, that makes sense. It is a reusable surgical device so maybe it could be considered but thank you.

Coordinator: Next question from (unintelligible) (Abraham), your line is open.

Mr. (Abraham): Hi, thank you for taking my question so my question is in regards to an existing device which has been modified and the associated risk exists for the predicate device, can the modified device but testing was not conducted on the predicate device but as of now the risk that has been identified with the modification requires you to do testing but there's no established standards for the testing or industry-recognized standards or literature?

Does since there's no established approach to testing, does that still make it eligible for the special 510(k) (pat) because you have the same intended us,

the design overall staying the same, it's just a smaller version of the existing device?

Angela DeMarco: So one of the eligibility factors is whether or not there are well-established methods and typically if there are no well-established methods for evaluating the change that you're making, then it most likely would not be eligible for a special 510(k).

Mr. (Abraham): Okay, all right. Thanks.

Coordinator: Next question from (David Chadwick). Your line is open.

(David Chadwick): Yes, good afternoon. Thanks for hosting this Webinar. So under the QUIK 510(k) program, FDA's restricted specific pro codes. Is anything really being restricted under this pilot or are all specials or submissions that are accepted as a special being put through the pilot? Thank you.

Angela DeMarco: So assuming 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 pilot.

(David Chadwick): Very good, thank you.

Coordinator: The next question is from (Elisa Maldonado Homens). Your line is open.

(Elisa Maldonado Homens): Yes, hello there. Sorry if I've already missed this but can we just to clarify can we still submit a Special 510(k) outside Special 510(k) program pilot?

Angela DeMarco: So currently with the Special 510(k) program pilot we are considering all 510(k)s that are marked as a Special 510(k) received on or after October 1st, 2018 as being part of the pilot program.

(Elisa Maldonado Homens): Okay, thank you. I just wanted to make sure that it wasn't the ones that had to be specified in the new RTA, okay, thanks, I appreciate it.

Angela DeMarco: Yes.

Coordinator: The next question's from (Joel Kent). Your line is open.

(Joel Kent): Yes, thanks again for hosting this. I have a question related to the eligibility criteria that relates to standards so sounds to me if we're able to declare conformity to a consensus, I mean, to a standard that FDA recognizes that even if that data was needed, you know, to be put in the Special 510(k) submission that that would still be eligible for the pilot?

And on the flip side if that is the case or even if it isn't, what happens if it's a non-recognized standard and we have to put the data in? Does that exclude us from being able to submit a special under the pilot program?

Angela DeMarco: So if the methods are considered to be well-established, we do expect that the results from that can be placed into a summary or risk analysis format. That hasn't changed from the existing Special 510(k) policy and typically if there is no well-established method for evaluating that change, then it would not be eligible for a Special 510(k) under this pilot program. Does that answer your question?

(Joel Kent): Well, yes, so it doesn't have to be an FDA-recognized standard, it could still be a well-recognized consensus standard that still has the right criteria, I

mean, I understand those should be few and far between but sometimes they're not.

Joshua Silverstein: Yes, I mean, that might end-up falling into the third prong of well-established methods which are those in the public domain.

(Joel Kent): Yes.

Joshua Silverstein: In terms of standards in general, FDA-recognized standards are the only type that we're allowed to accept the declaration of conformity to and so there's a little bit more benefit there in using them but, you know, if you thought that there was another standard out there that was relevant to your submission, you know, that's just something you might want to explain in your 510(k).

(Joel Kent): So it wouldn't bump us out of this necessarily, it might but it wouldn't automatically?

Joshua Silverstein: Not categorically.

(Joel Kent): Yes, I got you, thank you.

Coordinator: The next question from (Karen O'Troubcek), your line is open.

(Karen O'Troubcek): Hi, yes, thank you for taking my call. My question comes from the guidance also my understanding is from the guidance that clinical data is not accepted in support of changes to indications under the special 510(k) program.

Little bit of background, we had a request from the agency during the review of a traditional 510(k) to conduct a low-risk study towards the use of the device in a specific age group.

A little bit of background, we decided to defer back to the original age group but have since conducted this low-risk clinical study and we're nearing the end of it. Is this type of change to the indication based on this clinical support eligible for a special 510(k)?

Joshua Silverstein: In general, 510(k) submissions that rely on clinical data are going to still be scoped-out of the Special 510(k) program pilot but that's a very device-specific question that I'd recommend discussing with the reviewing division.

(Karen O'Troubcek): Okay, thank you so much.

Coordinator: Before we take the next question, as a reminder to ask a question at this time, please press star then 1 and record your name at the prompt. The next question is from (Fromica). Your line is open.

(Fromica): Hi, thank you for the opportunity to ask a question. I think the mainly the point is whether it's pulled into a Special or Traditional 510(k) but if the manufacturer believes the change is appropriate for Special 510(k) but in case actual documentation is enough, would the FDA tells that to manufacturer, it's like the conversion to a documentation occurred? Hello?

Angela DeMarco: One second.

(Fromica): Okay.

Angela DeMarco: Are you speaking to whether or not you would submit a letter to file such as you're making a determination as to whether or not a 510(k) is even needed?

(Fromica): Yes, it comes in, it's more, yes, that's true.

Angela DeMarco: Okay, so before submitting the 510(k) we do recommend that you determine whether or not the 510(k) is necessary and then once you do determine that it is or if you determine that it is, then you would review the eligibility factors for the Special 510(k) pilot to see if you meet those criteria.

(Fromica): Yes, my question is after that decision, after reviewing those points and the manufacturer so I would think they need Special 510(k)?

Angela DeMarco: So if you do submit the Special 510(k) and FDA determines that it is not eligible for or appropriate for Special 510(k) then we will notify you of that decision.

(Fromica): Okay, thank you.

Coordinator: The next question is from (Gayle Frueh), your line is open.

(Gayle Frueh): I have a question regarding submitting the 510(k). The slides stated that there is no change from the current method and that a hard copy duplicate is not required. This is the first time that I'm aware that a hard copy is not required so I'm wondering if this true only for Special 510(k)s and is there a guidance that documents this requirement that only an e-copy is required?

Angela DeMarco: So yes, it is relatively new but in September Federal Register notice was published that a hard copy duplicate is no longer required provided there is a valid eCopy so we were just for this Special 510(k) program pilot we were

just being consistent with that FR notice that went-out and that is for all 510(k) submissions and other premarket submissions as well.

(Gayle Frueh): Yes, okay, I thought we were waiting for a final rule on that, that's why I was totally confused but thank you.

(Marjorie): This is (Marjorie), it did publish but I think there was like a 60-day time to fully implement it but it's implemented now. We don't need hard copies for PMAs, 510(k)s, IDEs, pre-sub, any of it as long as you have a cover letter for the Center for Devices.

(Gayle Frueh): Okay, thank you very much.

Coordinator: The next question is from (Lee Lyker), your line is open.

(Lee Lyker): I know that you have said in previous response to previous questions that there are no pro codes, there are no codes that are exempted but would there be anything that would exempt it such as being designated as a combination product?

Joshua Silverstein: It would most likely depend on what kind of combination product it was so combination products are not excluded from the special 510(k) program ...

(Lee Lyker): Okay.

Joshua Silverstein: ... but depending on if it's, for example just a kit or something like that, might affect whether or not we could review combination products within a Special 510(k).

(Lee Lyker): And is a combination product let's say that it was consisting of a drug delivery device that was under 510(k) and a drug that was under an NDA or BLA. Would that be categorically excluded?

Joshua Silverstein: Categorically, no, but I would recommend explaining why you think they're well-established methods and - I'm sorry, I'm getting a little feedback - whether they're well-established methods and whether or not the data can be summarized and so if you could do that, if you could show that for your combination product, then it would be eligible to be reviewed in a Special 510(k) program.

(Lee Lyker): Thank you.

Joshua Silverstein: But it's really hard to categorically say they're in or they're out.

(Lee Lyker): Thank you very much.

Coordinator: The next question is from (Peggy), your line is open.

(Peggy): Yes, I just wanted to confirm that typical with every 510(k) part of that is you include catch-up to let the agency know of any note to file changes which were undertaken to the product.

Is that still appropriate to if your trigger for submitting a 510(k) falls under the special 510(k) program that you would still provide the information on the catch-up and that that alone wouldn't trigger you into a traditional?

Joshua Silverstein: Yes, so I think that's a little bit outside the scope of today's Webinar but there are device 510(k) modifications guidance, so I would recommend that

such changes be identified in a 510(k) and so I think it would still apply for a special.

(Peggy): Okay. Thank you and (Marjorie) could you mention what the Federal Register citation was because I had a discussion with several colleagues. They were surprised by the change in the policy for e-copy only which is fabulous by the way but I'd just like to share with them what Federal Register number that was?

(Marjorie): Yes, I have it right off the top of my head, no, I'm getting it from (Josh). (Unintelligible).

(Peggy): Yes. If somebody could just look it up during the call and throw it out, that would be great.

(Marjorie): All right.

Joshua Silverstein: We're on it.

Coordinator: The next question is from (Mike Pearson), your line is open.

(Mike Pearson): Oh hi there. I'm just wondering if you could clarify what is meant by whether or not performance testing is required because in most cases of change there is some internal verification validation testing that's done. Obviously these aren't always well-established because they're just internal to them. Could you clarify what's meant by the performance testing?

Joshua Silverstein: Sure, thanks for your question. So one great example of that is maybe you have an implant device and your labeling for your cleared product does not

address MR compatibility and now you'd like to say that your device is MR safe and that's based on a scientific rationale.

And you've made the assessment that you need a 510(k) and so in that particular case no performance data would be necessary to establish substantial equivalence because your 510(k) would be based on a scientific justification.

(Mike Pearson): Okay, so any internal testing that you do for like I don't know, usability testing or things that aren't necessarily well-established because they're based on an internal protocol that would not preclude this special 510(k)?

Joshua Silverstein: We do see a lot of usability like testing in special 510(k)s as part of design validation and so you are right that most 510(k)s do have some kind of performance data in them and I think what you just need to focus-on is what kind of information you need to submit to the agency to establish substantial equivalence.

If you believe that the usability testing or, you know, sort of like the design validation testing is necessary, then you would include that but it's hard to categorically say that you should never submit that because we do often see that kind of testing in a special 510(k).

(Mike Pearson): Okay, thank you very much.

(Marjorie): This is (Marjorie) again and if I could make a correction on what I said before. The Federal Register that's out there is a proposed rule and that number is the docket number is FDA-2018-N-0628 and we're looking for comments by December 12th. However, our document center is not putting files on hold for lack of a paper copy at this time but it is a proposed rule.

Coordinator: The next question comes from (Elijah Atkinson), your line is open.

(Elijah Atkinson): I think you already kind of touched-on this but I wanted to clarify the well-established methods. It had to do with the usability testing the last person was just asking about.

When we do that design validation testing and we have something that we're evaluating in a traditional 510(k) and then we do some sort of design change and we want to submit a special 510(k), could we consider that usability testing we had done previously as a well-established method?

Joshua Silverstein: Yes.

(Elijah Atkinson): Okay, the follow-up question to that is often times you know, over the years we tend to learn with these internal test methods about what works, what doesn't. We improve, we, you know, have we realized that certain tissues worked better and they kind of evolve over time, if they aren't the exact same test method, I would think that in good faith you could still consider it a well-established method. Does that make sense?

Angela DeMarco: Yes, it does make sense so if you do make modifications to that previously-used method, we do expect that you explain those modifications and kind of justify why it still does count as a well-established method.

(Elijah Atkinson): Okay, thank you, appreciate your time.

Angela DeMarco: Yes.

Coordinator: The next question from (Robert Packard), your line is open.

(Robert Packard): Yes, for companies that are making a change for the indications for use where you're switching from adult-only to pediatric and adults, things like flow rates and size of course would need a change, there are going to be some potential validation methods that are needed, would that be expected to still be within the scope of acceptable for a Special 510(k)?

Angela DeMarco: So if you have a well-established method for evaluating this and can summarize the data, then it would be appropriate for a Special.

(Robert Packard): Thank you.

Coordinator: The next question from (Andras Rodrigues), your line is open.

(Andras Rodrigues): My question was kind of answered a few questions ago but basically if you guys once accepted methods for an indication for use and we use that same method for the same indication, is that considered a well-established method?

Joshua Silverstein: Could you be a little bit more specific about what the method was evaluating?

(Andras Rodrigues): Sure, it was an animal model for indication for use and for general bone graft substitute and we would for this new device with a slight material change, we would going to basically repeat the same study to prove equivalence with the predicate.

Joshua Silverstein: Yes, I mean, so typically we think that animal studies are outside the scope of the Special 510(k) program and assuming that you made an argument that there's a well-established method, you might still end-up with a

conversion because FDA would still want to look at the underlying data around that animal method.

(Andras Rodrigues): Okay, thank you.

Coordinator: And once again at this time to ask your question, please press star 1 and record your name at the prompt. The next question comes from (Marianne Egley), your line is open.

(Marianne Egley): Good afternoon and thank you, everyone for giving me this opportunity. I would like to just clarify what a previous person asked about catch-up 510(k) so if I have a cleared device in which I have internally filed multiple letters to file against because by virtue of the assessment it did not trigger a 510(k), when I submit the Special 510(k) I should include all the details of the letters to file, is that correct?

Joshua Silverstein: So I think this question is a little bit outside the scope of today's Webinar. I'd just like to refer you back to the 510(k) device modifications guidance for more information.

(Marianne Egley): Okay, thank you.

(Marjorie): Yes, this is (Marjorie). I just want to add that most likely we're looking for information just on the change for this new 510(k) which is the subject of the special. If those incremental changes have to do with this change, then I think they would be an important part of the special but you have to remember that a number of changes can actually turn the device into a brand new device and it might just be easiest to start with the traditional anyway.

(Marianne Egley): Okay, good input, thank you (Marjorie).

Coordinator: We are showing no further questions. We'll turn it back over to Irene Aihie for closing remarks.

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 Monday, November 19th.

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 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. This concludes today's Webinar.

Coordinator: Thank you. Once again that does conclude today's conference. We appreciate you attending. You may disconnect at this time.

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