Case Study: Material Substitutions in Devices Subject to Premarket Notification [510(k)] Using Polytetrafluoroethylene (PTFE) December 10, 2025

Moderator: CAPT Kim Piermatteo
Presenters: Dr. Ed Margerrison, Dr. Ryan Ortega and Dr. Annie Powell
Additional Panelists: Dr. Kira Moore, Dr. Jinny Liu and Angela Krueger

Slide 1

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Slide 2

CAPT Kim Piermatteo: Hello everyone and welcome to today's CDRH Webinar. Thanks for joining us. This is CAPT Kim Piermatteo of the United States Public Health Service and I serve as the Education Program Administrator in the Division of Industry and Consumer Education within CDRH. I'll be the moderator for today.

For this webinar, we will be discussing a Case Study on Material Substitutions in Devices Subject to Premarket Notification or 510(k), Using Polytetrafluoroethylene or PTFE.

Our presenters are Dr. Ed Margerrison, Director of CDRH's Office of Science and Engineering Laboratories; Dr. Ryan Ortega, Regulatory Advisor and Biomedical Engineer in CDRH's Office of Product Evaluation and Quality; and Dr. Annie Powell, Senior Fellow in the Divisions of Biology, Chemistry and Materials Science in CDRH's Office of Science and Engineering Laboratories.

We'll begin with presentations from our presenters and then have a moderated panel discussion.

Before I turn it over to Ed to get us started I'd like to provide two reminders. First, the intended audience for this webinar is industry. National media and press members are encouraged to submit their questions through the FDA Newsroom at www.fda.gov/news-events/fda-newsroom. Second, for those of you who may want to follow along, you may access printable slides of today's presentation from CDRH Learn at www.fda.gov/Training/CDRHLearn under the section titled "How to Study and Market Your Device," sub-section "Premarket Notification [510(k)]."

Again, thank you all for joining us today. I'll now turn it over to Ed to start today's presentation.

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Dr. Ed Margerrison: Thanks Kim. I'm Ed Margerrison, the Director of the Office of Science and Engineering Labs at CDRH, and today we'd like to provide further clarity for those situations where the substitution or changing of materials is required in medical devices subject to 510(k) regulation. Please note that all discussions today are limited to those devices subject to 510(k) and no parallel with other devices should be assumed.

These changes may be necessary for a myriad of reasons, and situations can change very rapidly and in unexpected and unpredictable ways. Our intention today is to clarify and discuss considerations for such changes within the scope of existing guidance so that the least burdensome approach to keeping medical devices available for patients can be followed.

We will refer to all of these as material substitutions or material changes during this webinar. The overall scope should be considered to include changes in manufacturing and processing aids, as well as

changes to materials of construction. Please note that the focus of this webinar is not intended to cover in vitro diagnostics.

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Dr. Ed Margerrison: The final guidance entitled “Deciding When to Submit a 510(k) for a Change to an Existing Device” was issued in 2017 and is the most relevant document for our discussions today.

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Dr. Ed Margerrison: Our learning objectives for this webinar are shown here. In trying to clarify and explain approaches needed for material substitutions for 510(k) devices, we will use polytetrafluoroethylene or PTFE as an example. It’s very much top of mind for many companies right now and I would like to take a few minutes to set the scene and explain a little why we have chosen this material as a good example for discussion.

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No audio.

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Dr. Ed Margerrison: There has been significant public interest in the subject of per and poly fluoro alcohol substances, known as PFAS, in recent months and years. The whole category of PFAS encompasses a wide range of chemical compounds with a very diverse spectrum of properties. Different PFAS compounds can have very different toxicological and chemical properties, and a blanket statement regarding safety, or lack thereof, is not always helpful. CDRH’s perspective on the use of PFAS in medical devices is available on our website. In particular, it is important to consider fluoropolymers such as PTFE distinctly from the short chain PFAS that have been linked to a number of human health concerns.

PTFE has been used safely in medical devices for many decades, but recent market exits of a number of fluoropolymer manufacturers has resulted in a flurry of activity across the Medtech community to find alternative suppliers and substitute grades of material.

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Dr. Ed Margerrison: We do understand that material changes, for strategic reasons or unpredictable events, are a complicated and frequent occurrence, but at the end of the day I believe we all want the same thing, to ensure continued supply of devices to patients with a least burdensome transition plan that assures safety and effectiveness.

Part of that plan involves ensuring that the appropriate assessment is conducted and documented, and if required, submitted to FDA. We will be discussing considerations for that over the next few minutes.

I’ll now turn it over to Dr. Ryan Ortega.

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Dr. Ryan Ortega: Thanks Ed. I’ll now discuss the 510(k) Mods Guidance.

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Dr. Ryan Ortega: As Ed said, my name is Ryan Ortega and I’m going to talk to you about our 510(k) modifications guidance or Mods Guidance. You can reach this guidance at the URL on the slide.

This guidance describes a policy for determining when a 510(k) is required for a change to a cleared device and it uses flow charts and explanatory text to guide you through this framework. Per the guidance, a key question you should be asking yourself is, could this change significantly affect safety or effectiveness of the cleared device?"

Since we are using a PTFE-to-PTFE material change as the case study, let's assume that this material change is being made because a device manufacturer needs to go from one PTFE supplier to another. The change isn't being made with the express intent to significantly improve the safety or effectiveness of the device, the plan isn't to make a labeling change, and the goal here is to ensure that the material change isn't changing the device technology or performance. It's really simply a like-for-like material change. In that case I'd like for us to go right to the "Materials Changes" flowchart and framework in the guidance.

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Dr. Ryan Ortega: Section C of the guidance is specific to materials changes. It focuses on a risk assessment of material changes using similar biocompatibility risk assessment principles as described in FDA's biocompatibility guidance. Now, for the purposes of our example, we've identified that the change is a material change, and we can answer the first question in the flowchart by saying it's a therapeutic device, not an in vitro diagnostic device. Then we confirm it's a change in material type, formulation, composition or processing, and it is in direct or indirect contact with body tissue or fluids.

Slide 12

Dr. Ryan Ortega: Now we can work on assessing if the new material has any new or increased biocompatibility concerns compared to the unmodified material. Annie will say a little bit more about risk assessments in a few slides, but very briefly, your risk assessment may consider risks posed by the new material to the patient or user. An example of a new concern would be say if the material change meant that you now have to assess additional biocompatibility endpoints, relative to the previous version of the device. An example of an increased concern could be a significant increase in a risk that's found when assessing one of the same biocompatibility endpoints as was considered for the previous version of the device.

I really want to stress that our guidance says that the answer to C4 may be a no if a knowledgeable individual reviews the differences in chemical composition or physical properties and determines that the change is minor enough that there is no new concern about biocompatibility and internally documents their assessment.

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Dr. Ryan Ortega: If your risk assessment ultimately identifies new or increased biocompatibility concerns, you may still be able to assess if the same material has been used by the same manufacturer in a similar device. If so, you may be able to determine that the new material could not significantly affect safety or effectiveness. If not, a new 510(k) could be required. If there are no new or increased biocompatibility concerns, you should also assess if the change could affect device performance. If so, you would also evaluate the change as a technology change. Finally, I want to flag for you that there are examples in the guidance that include material changes.

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Dr. Ryan Ortega: Ok, so let's say you've made a PTFE-to-PTFE material change in your 510(k) cleared device, and you've determined that a new 510(k) is not needed. How do you document that decision? Most 510(k) devices must comply with quality systems regulations, which require documentation of design changes prior to implementation. Documentation is particularly important when you determine a 510(k) is not required. Appendix B in the Mods Guidance recommends some basic elements of good

documentation that every manufacturer can use. It also provides some examples of documentation that can be adapted to the complexity of a given change, and you can use these or adapt these as needed.

And we recommend that your documentation include some basic information about the device and its regulatory history, as well as an explanation for why you're implementing this change. It also helps to include a comparison of the changed device to the previous iteration of the device.

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Dr. Ryan Ortega: We also recommend that you utilize this guidance document's framework to the extent possible for your internal documentation. The questions in the flowcharts provide a useful, logical framework for explaining your assessment and the rationale for the change, as well as how you concluded that a new submission isn't needed. I want to note that only highlighting the flow chart in this guidance document or simply answering "yes" or "no" to each question without further details or justification isn't really considered sufficient documentation, and we recommend that you include your actual analysis and link your documentation to any important reference documents, say like a risk assessment, that would support the change.

Ultimately, the documentation should be prepared in a way such that an FDA inspector or some other third party can understand what the change is and the rationale underlying your conclusion that submission of a new 510(k) is not required. Your determination that a new 510(k) is not needed should be supported by your risk assessment and confirmed by any verification and validation activities that you conduct.

Now I'll turn it over to Annie to talk a little bit about the practice of conducting a risk assessment to support a material change for a device.

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Dr. Annie Powell: Thank you, Ryan.

Slide 17 [with added context]

Dr. Annie Powell: Section E of the Mods Guidance contains considerations for addressing risk-based assessment of modified devices. CDRH Learn has a number of additional resources related to further considerations for risk assessment.

[Due to a technical issue the following content was not spoken during the live event and is being provided in the transcript as additional context for this slide.

Links to those will be provided towards the end of the presentation section of this webinar. I would particularly like to draw your attention to the definition of risk, as per the guidance, "The combination of the probability of occurrence of harm and the severity of that harm. For the purposes of this guidance, may relate to either safety or effectiveness", for example risk of decreasing device effectiveness.

FDA recommends that manufacturers use an accepted method of risk assessment, such as ISO 14971, which is an FDA-recognized standard that provides a framework for systematically managing risks of medical devices throughout the total product life cycle.

*Please also note that, as stated on the current slide, it is not necessary to address hypothetical risks if they are likely to have a negligible impact on the conclusions of the risk assessment and that if the likelihood of harm occurring to a device change is negligible, then the change is unlikely to require a new 510(k). So, industry's responsibility is to conduct an objective and professional risk assessment which is pivotal in a sponsor's approach to navigating the required steps of any change.***]**

Dr. Annie Powell: Let's consider the specific case of a PTFE-to-PTFE substitution in a device that is subject to 510(k) regulations. As Ryan said, the 510(k) Mods Guidance can be used and specifically section C. If we assume that the PTFE is a material of construction and not a processing aid, although the same considerations might apply, and that the substitution of the raw material did not necessitate any processing parameter changes, nor product specification changes, and that the manufactured product meets the original product specifications with comparable results, then we have the simplest case to consider.

The risk analysis would likely demonstrate that there are no new or increased biocompatibility concerns in step C4 and the performance has been demonstrated to be unchanged. This case study therefore allowed the sponsor to document the change internally, for example in a letter to file. If, however, the PTFE substitution resulted in changes to the design or product specifications, then it is possible that a new premarket notification could be required.

Situations can obviously be more complex than this one, but the same logic and principles should be applied to determine the appropriate pathway to follow. It is worth pointing out that in the situation where internal documentation is the appropriate way to document the change, then information concerning the change should not be submitted to the FDA for consideration. If a new 510(k) is required as per the guidance, then relevant information should be included in the 510(k).

I'll now turn it back over to Ed.

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Dr. Annie Powell: Let's consider the specific case of a PTFE-to-PTFE substitution in a device that is subject to 510(k) regulations. As Ryan said, the 510(k) Mods Guidance can be used…

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Dr. Ed Margerrison: Thank you Ryan and Annie. On the screen are some useful resources that we have specifically referred to in this presentation. I'll give you a few seconds to write notes if you wish.

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Dr. Ed Margerrison: In summary, we have attempted to demonstrate use of the 510(k) Mods Guidance to help you, as sponsors and manufacturers, determine the appropriate steps needed in those situations where changes occur, either by intent or outside factors. I shall now hand back to Kim to continue the webinar.

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CAPT Kim Piermatteo: Hi Ed, thanks for that. I think we did have a glitch there, so I do apologize to everyone. We will try to fix that on our end. So just give me one second. I think, Ed, do we want to go back and just touch on that one slide?

Dr. Ed Margerrison: Yeah, I think we should touch on that slide. That one slide from Annie because it jumped around a little bit. I'm not sure exactly what happened, Kim.

CAPT Kim Piermatteo: Yeah, I mean.

Dr. Ed Margerrison: Is it easy to do that and play that one slide of Annie's? Cause I think she got cut off a bit.

CAPT Kim Piermatteo: Yes, and I apologize for that. Just experiencing a little bit of an IT issue. So for our attendees, what I'm going to do is we're going to go back. Annie, I believe it was on slide. Let me go back. Hold on, Annie.

Slide 17 [Slide repeated due to a technical issue.]

CAPT Kim Piermatteo: It was this slide right, Annie? I apologize.

Dr. Annie Powell: I think it cut out on the next one.

Dr. Ed Margerrison: Yeah, we got all of that one, Kim. It was from the start of the next one.

CAPT Kim Piermatteo: Okay. Let me see if I can get that back. Annie, hold on one second.

Slide 18 [Slide repeated due to a technical issue.]

Dr. Annie Powell: Let's consider the specific case of a PTFE-to-PTFE substitution…

CAPT Kim Piermatteo: One second again.

Dr. Annie Powell: … in a device that is subject to 510(k) regulations. As Ryan said, the 510(k) Mods Guidance can be used and specifically section C. If we assume that the PTFE is a material of construction and not a processing aid, although the same considerations might apply, and that the substitution of the raw material did not necessitate any processing parameter changes, nor product specification changes, and that the manufactured product meets the original product specifications with comparable results, then we have the simplest case to consider.

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I'll now turn it back over to Ed.

Slide 21

CAPT Kim Piermatteo: Thanks Annie. Okay, sorry again about that little hiccup there, but I hope whenever we do post the transcript and the recording, we will try to make sure that it is more seamless for you. If you wish to listen to it, then.

So we'll now transition to our moderated panel discussion. Just for your information, we will not be taking questions from our attendees today. Therefore, please refrain from raising your hand in Teams.

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CAPT Kim Piermatteo: Joining our presenters today for this panel discussion are; Dr. Kira Moore, Senior Health Scientist in the Office of Supply Chain Resilience in CDRH's Office of Strategic Partnerships and Technology Innovation; Dr. Jinny Liu, Lead Chemist on the Intraocular Lens and Accessory Devices

Team within CDRH's Office of Product Evaluation and Quality; and Angela Krueger, Deputy Office Director for Regulatory Policy in CDRH's Office of Product Evaluation and Quality, as well.

So thank you all for joining us.

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CAPT Kim Piermatteo: For today's panel discussion, I'll read a frequently asked question regarding our topic and then ask a panelist to respond.

Our first question, first up is Kira. I have a question for you, and that question is, can I use the same approach for materials other than PTFE?

Dr. Kira Moore: Thanks for the question. Yes, the guidance is not specific for PTFE or any other material. The process can be broadly applied.

CAPT Kim Piermatteo: Thank you, Kira. The next question I have, I'm going to direct this one to you, Jinny. This question is, if I determine that documentation is sufficient, can I submit supporting information to the FDA?

Dr. Jinny Liu: Thank you, Kim for your question. No, we don't recommend this. Please maintain the documentation in your 510(k) file that you keep in your internal records. Back to you Kim.

CAPT Kim Piermatteo: Thanks Jinny. Alright, for the next question, I'm going to direct this one to Angie. Angie, the question is, what about PMAs or premarket approval applications?

Angela Krueger: Thanks Kim. The current scope of this exercise was related to 510(k)s. The approach we discussed during this webinar is for devices specific to 510(k) regulation.

Don't forget though that there guidances specifically available for devices subject to PMA regulation, which cover the steps required for material changes for Class 3 devices. In general, guidances that may be relevant to you for making changes to PMA approved devices include, our PMA modifications guidance, titled "Modifications to Devices Subject to Premarket Approval - The PMA Supplement Decision-Making Process"; second our guidance on 30-day notices and 135-day PMA supplements, titled "30-Day Notices, 135-Day Premarket Approval (PMA) Supplements and 75-Day Humanitarian Device Exemption (HDE) Supplements for Manufacturing Method or Process Changes"; and third, our enforcement policy guidance on certain changes for PMA devices intended to help mitigate shortages, titled "Enforcement Policy for Certain Supplements for Approved Premarket Approval (PMA) or Humanitarian Device Exemption (HDE) Submissions."

We would encourage you to consider how these guidances and policies might apply to your specific situation. If you have detailed questions, you can certainly reach out to us.

CAPT Kim Piermatteo: Great. Thanks Angie. I actually want to come back to you, Angie, for another question. And that question is, can I use PCCPs or predetermined change control plan approach?

Angela Krueger: Everybody's favorite answer. It depends. What I would say here is keep in mind that PCCPs are generally appropriate for certain modifications that would otherwise require a new marketing submission. So for example, if you would otherwise simply use internal documentation to support the change for a previously cleared device, that sort of change would likely not be appropriate for a PCCP.

The other thing to keep in mind is that in order to authorize the PCCP, we would need a submission, we would need to review it. So submitting a PCCP for a single change that you would have to submit a new 510(k) for anyway might not be the best use of that regulatory tool.

In the context of PTFE related materials changes, if you think you may need to make a series of changes over time to a previously clear device or perhaps you're anticipating having to make future material changes to a new device, a PCCP might be a useful tool to help facilitate those changes and at least burdensome fashion.

CAPT Kim Piermatteo: Great. Thanks Angie. For our next question, I'm going to direct that question to Jinny. And Jinny, that question is, what level of material information and/or material qualifications data would FDA like to see?

Dr. Jinny Liu: Thanks Kim. So we would refer you to the 510(k) Mods Guidance in these situations. There is sufficient information in there for you to determine the relevant information.

CAPT Kim Piermatteo: Thanks Jinny. I think we cut out just a little bit at the end, but I think you were basically saying to determine what information should be sufficient, right?

Dr. Jinny Liu: Yes, refer to the 510(k) Mods Guidance.

CAPT Kim Piermatteo: Okay, perfect. Thanks Jinny. Alright, Ed, I'm going to come to you with a question. The question is, why is the shortage anticipated?

Dr. Ed Margerrison: Thanks, Kim. I think that's a really important question actually. We're certainly not saying that we would anticipate a shortage in PTFE. But working with a lot of the community, we've become very aware that several major manufacturers of fluoropolymers in the U.S. have announced publicly that they are exiting the market or restructuring their PFAS/fluoropolymer business.

So rather than just let it happen, we've been trying to work proactively with everyone. So the withdrawal of some of these companies from manufacture has both direct and potentially an indirect effect impacting the availability of some of those raw materials for production. So even though a particular grade might be still available on the market, it might be that the precursors are not available, so we know there is the potential for some disruption. So we're trying to together trying get ahead of the game. Thanks Kim.

CAPT Kim Piermatteo: Thanks Ed. Alright Angie, I'm going to come back to you. This question is, the focus seems to be on Class 2 devices, what about Class 3 or implantable Class 2 devices?

Angela Krueger: Thanks Kim. You know, part of the reason that we focused on Class 2 devices, you know today was really because that is the largest regulatory review program that we manage. And so we limited the scope for purposes of this webinar. For Class 3 or implantable Class 2 devices as mentioned there are other guidance documents that may be available that are applicable in those situations. And we think those guidances maybe relevant. You know, one example is the PMA supplements guidance. And we also have the manufacturing site change document, guidance document which may be applicable depending on the specific situation.

CAPT Kim Piermatteo: Great. Thanks Angie. Alright, for our next question, I'm going to direct that to Kira. Kira, the question is, how many implantable devices, including tooling or manufacturing aids, are impacted by the supplier change?

Dr. Kira Moore: Thank you, Kim. We don't know. We wouldn't necessarily be familiar with all the processing aids that a company might use. Even though during today's webinar we focused primarily on PTFE, there are a number of other fluoropolymers used in devices, PVDF, ETFE, etc. And change is a fact of life across the Medtech space.

CAPT Kim Piermatteo: Good points. Thank you, Kira. Okay, Annie, I have a question for you. Annie, the question I want to ask you is, what if we conduct our risk assessment and we identify new or increased biocompatibility concerns and decide a new 510(k) is needed? What do we need to submit?

Dr. Annie Powell: I would suggest that you refer to the 510(k) Mods Guidance for detailed information. The new 510(k) should describe all the changes that triggered the requirement. Changes that don't trigger the requirement should also be described if they would have been described in the original 510(k) for that device.

CAPT Kim Piermatteo: Great. And another question for you, Annie, is for a new 510(k), can I use the original product before substitution as the predicate?

Dr. Annie Powell: If that is the most appropriate choice, then yes, that would be acceptable. Thanks, Kim.

CAPT Kim Piermatteo: Thanks Annie. Coming back to you, Angie, the next question I have is, can you clarify when we should use the modifications approach rather than an Abbreviated or Special 510(k)?

Angela Krueger: Sure. Thanks, Kim. You know, first you really need to determine if a submission is needed. So if you determine that a change can be supported with internal documentation, for example, then that would mean a new 510(k) is not needed, and that would include Abbreviated and Special 510(k)s too. The utility of our Abbreviated and Special 510(k) programs is likely to be fairly case specific for PTFE-to-PTFE changes. So if you determine that your change needs a new 510(k) and you're considering if those pathways might be an option for you, I suggest, I would suggest looking at our guidances that are specific to those programs, both the Abbreviated and Special 510(k) pathways have their own guidances which you can find on our website and may be helpful in determining which approach to take.

CAPT Kim Piermatteo: Great. Thanks Angie. Annie, though, I'm going to come back to you. The question I have is, if documentation is the requirement, what are the specifics that I need to comply with?

Dr. Annie Powell: For this one, I would refer to the 510(k) Mods Guidance Appendix B and the information that was outlined earlier in Ryan's presentation.

CAPT Kim Piermatteo: Gotcha. Thank you, Annie. Alright, Jinny, another question that we have is, what fluoropolymers other than PTFE are used in medical devices?

Dr. Jinny Liu: Thanks Kim. So to our knowledge, there are about four commonly used fluoropolymers in medical device. So other than PTFE, there are also ETFE, FEP, and PVDF. It is believed that about 80-90% of the usage is with PTFE, including expanded PTFE.

CAPT Kim Piermatteo: Thank you, Jinny. Good points. Alright, Ed, we have one more question and then we will move to wrap up our panel discussion. And Ed, that question I have for you is, are there functional substitutes for fluoropolymers?

Dr. Ed Margerrison: That's a big question. I think it's easiest to say really not at this time. Fluoropolymers are very unique molecules and they've got a set of properties that really to date haven't been all incorporated in one set of materials and they have things like very low coefficient of friction. Interesting electrical resistivity properties and things like that that make them actually really quite uniquely suited for a lot of their functions within devices. And we've been asked this on a number of occasions actually and how long it might take to make those substitutes and the only answer we've really got is we don't know because those things really haven't been invented at this time. And I think there's many people on this call who are probably much better qualified than I am to talk about that in depth, so I'll hand back to you, Kim, at that point.

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CAPT Kim Piermatteo: Great. Thanks, Ed. Okay as I mentioned that will wrap up our panel discussion for this webinar. Again, thank you to all of our presenters and panelists for participating today and sharing

your expertise and thoughts on this topic. At this point, Ed, I'm going to turn it back over to you to provide some final thoughts.

Dr. Ed Margerrison: Okay, thanks Kim. First and foremost, thanks to everybody who registered and logged on to this webinar. Hope it's been useful.

We've really tried to do a couple of things. The first was to refresh all of our memories on applying 510(k) Mods Guidance to changes in materials of construction for the right sort of devices, and just to reiterate, and I apologize if this sounds a little bit repetitive, but it really is the key of what we've tried to discuss. There are two major questions that we expect people to address, the first is does a risk assessment identify any new or increased biocompatibility concerns? And as we've said and Annie went through, we recommend using an accepted, well recognized risk assessment process. Probably the best known is ISO 14971. And the current version of that which was published in December 2019, is fully recognized by FDA. And to reiterate again that the answer to that question C4 may be no if a knowledgeable individual reviews the differences in chemical composition etc. and determines that there is no new concern about biocompatibility. That very much starts pointing you towards the potential for documentation of any change.

And the secondary question, which we alluded to earlier on is, does that change or could that change affect the device's performance specifications? And again, if the product is performing within specification and that specification hasn't changed, then it starts leading you towards a documentation.

Secondarily, the thing that we tried to discuss a little bit is that as I said earlier, there are many companies that are going through PTFE substitutions right now for their existing devices. And that's because some commercial grades are becoming unavailable on the open market. What we're trying to get across is that using the Mods Guidance for those devices that are subject to 510(k) and using that outline that we've described, we're really hoping that sponsors can take a consistent and an appropriate approach to whether a new premarket notification maybe required or if internal documentation is appropriate.

As we said in the panel as well, although we are focused on PTFE, the same principles described in that Mods Guidance can apply to other substitutions or changes in materials of construction or some other materials that are used in manufacturing. And if there's one thing I've learned in my career during medical devices, the breadth of situations does sometimes seem almost infinite. So it's quite possible that we haven't been able to answer all of your questions, but we always encourage a dialogue so that together we can decide on the most appropriate path forwards.

My final comment before I hand back to you, Kim. It's a plea really to please do let us know if you become aware that there may be imminent changes to common materials of construction used in devices. It certainly allows us to keep ahead of all of those changing situations and together then we can do what we can to ensure that any transition is managed as smoothly as we possibly can.

And with that, Kim, I shall thank everyone again for their attendance and being participants in this and I'll hand back to you.

CAPT Kim Piermatteo: Thanks Ed. So on my end, just a few closing remarks, I just want to remind everyone a recording of today's webinar and a transcript will be posted in the next few weeks to the webinar event page as well as to CDRH Learn under that section titled "How to Study and Market Your Device," and the sub-section "Premarket Notification [510(k)]." And a screen shot of where you can find these materials on CDRH Learn has been provided on this slide.

If you have any additional general questions regarding today's webinar, feel free to reach out to us in DICE at DICE@fda.hhs.gov.

And lastly, I encourage you to monitor our CDRH Events webpage for a list of upcoming CDRH Events, including future webinars. And that link is www.fda.gov/CDRHevents.

Thank you all again for joining us. We hope you found today's presentations and panel discussion informative. And this concludes today's CDRH Webinar.

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No audio.