FDA Webinar: Multiple Function Device Products:
Policy and Considerations
Moderator: Irene Aihie
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Coordinator: Welcome and thank you for standing by. At this time, all participants are in a listen-only mode until the question and answer session of today's conference. At that time, you may press star one on your phone to ask a question.

I would like to inform all parties that today's call is being recorded. If you have any objections, you may disconnect at this time.

I would now like to turn to the conference over to Ms. Irene Aihie. Thank you. You may begin.

Irene Aihie: Thank you. Hello. And welcome to today's FDA Webinar. I am Irene Aihie of CDRH's Office of Communication and Education. On July 29, 2020, the FDA issued its final guidance, Multiple Function Device products: Policy and Considerations. This final guidance incorporates feedbacks from public comments to clarify and provide examples that describe the FDA's policy on product with multiple function. It also describes medical software positions of the 21s Century Cures Act as part of the FDA's long-term Digital Health Innovation Action Plan and identifies the principles, premarket review practices and policies for the FDA's regulatory assessment of products with multiple function that include at least one device function.

Today, Sonja Fulmer, Assistant Director for Digital Health Policy in the Office of Strategic Partnership and Technology Innovation, in the Division of Digital Health here in CDRH will present an overview of the guidance. She is

joined by other centers subject matter expert to assist with the Q&A. Following the presentation, we will open the lines for your questions related to information provided during today's discussion.

Now, I give you Sonja.

Sonja Fulmer: Good morning. Thank you for that introduction Irene and thank you to everyone joining online for today's webinar on the multiple function device products guidance. Next slide.

Today, I'll start by providing background information on the software provisions of the 21st Century Cures Act. Then, we'll discuss the definitions of terms that we use in the guidance in this webinar before moving into the details of the final guidance. We'll conclude with some additional resources that you can access if you have further questions about this guidance.

Next slide.

At the end of this webinar, you should be familiar with the few key terms including how we define functions for the purposes of this guidance. You should understand FDA's regulatory approach and policy for all multiple function device products. You'll also be familiar with considerations you should keep in mind for the design and risks of these products. You should understand how FDA intends to assess the impacts of non-device functions or other functions on the safety and effectiveness of a device function in addition to knowing what premarket submission content is recommended for a device function under review that is part of a multiple function device product. Next slide.

This slide describes the basis of FDA's regulation of software. First and foremost, we take a risk based approach to the regulation software. Importantly and especially for this guidance, that approach is focused on a specific functions of devices, and the regulation is narrowly tailored to the risk of the devices. These approaches are platform independent, meaning that it does not matter on what type of platform the software function is deployed

from a general purpose competing platform to a smartphone, we apply our regulation based on the function.

This is intended to promote innovation and patient engagement with these digital health products. And ultimately, to protect patient safety. The software provisions of the 21st Century Cures Act built from this approach to the regulation of software. Next slide.

The Cures Act recognized that there are certain digital health products that are low risk. Many of these products were under enforcement discretion policies prior to the enactment of the Cures Act which codified many of those existing policies by revising the definition of device to exclude certain low software functions. This enabled FDA to apply a least burdensome approach for device regulation. Next slide.

As I mentioned, the Cures Act defined software functions that are not device functions. It also states that FDA shall not regulate non-device software functions of a product with multiple functions but we can consider the impact if this non-device functions on the safety and effectiveness of the device functions. Next.

And as you know, this is the topic -- this topic is the focus of the guidance we're discussing today. The Cures Act also provides for the FDA regulation of software functions that are excluded from the device definition if we find that those functions will be reasonably likely to have serious adverse health consequences.

In order to do that, there are certain substance and procedural criteria that must be met. And these exclusions from the device definition don't include software functions involved in the manufacture and transfusion of blood and blood components to assist in the prevention of disease in humans. Next slide.

We've often described the Cures Act as codifying some existing FDA policies, including those for software functions intended for administrative support, general wellness, electronic patient records, those intended for the transfer

storage, converting -- conversion of formats and display of medical device data, and certain clinical decision support functions. Next.

What we have talked about last is the regulation of multiple function device products. The Cures Act was also a recognition of our approach to those types of products. In that FDA does not regulate non-device functions but we can consider the impacts those functions have on the devices we do regulate. Next slide.

Here is the full text of a multiple function statutory provision which was added to Section 520(o) of the Federal Food, Drug and Cosmetic Act. Simply put this provision says that FDA does not regulate non-device software functions and that we can assess the impacts of those software functions on device functions. In the guidance we're discussing today, we describe how that works in practice. Next slide. And next.

The guidance describes the overarching policy of premarket review of multifunction device products. Next. It also describes what manufacturers should consider for those products. Next. The questions to ask when assessing the impact on the device function. Next. And the recommend the content of a premarket submission for these multiple function device products. Next.

So before we get into those sections, we're going to go over some definitions of a few terms that we use for the purposes of this guidance. First the term function is the distinct purpose of a product. It could be the intended use or subset of the intended use. By way of a simple example, a product could have just one function: to analyze data.

A multiple function product could be intended to store, transfer and analyze data and those are three functions. A device function is a function that meets the definition of a device according to Section 201(h). An other function can be a function that does not meet the definition of device or it meets the definition of device but it's not subject to premarket review like a 510(k) exempt device. Or it can be a function that meets the definition of device but is one that FDA has expressed its intent not to enforce compliance with the

applicable regulatory controls. That's what we often describe as a function under enforcement discretion.

A device function under review is a clunky term for the function for which FDA is conducting a premarket review. And a multiple function device product is a product that contains at least one device function and at least one other function. Next.

The Cures Act multiple function provision is limited to multiple function products that contain non-device software functions. However, the principles in this guidance apply to the assessment of all multiple function device products, whether these functions are software-based, hardware-based, or both.

In the premarket review context, this means a multiple function device product is a product with at least one device function under review and one other function. And although the guidance mostly focuses on premarket, the principals still apply in the post-market context.

In that context, a multiple function device product is a product with at least one device function that is the focus of the FDA's oversight and one other function. So for example in the post-market context, during a -- during an inspection of a facility manufacturing a multiple function device product, the principles of these guidance would apply to a 510(k) exempt device function. Next. Next.

Irene Aihie: Sonja, do you see my slides progressing?

Sonja Fulmer: Yes. Sorry. I think we're now on slide 13. I think I may have had a delay on my end. So appreciate that.

So, we are now onto the Policy for Pre-market Review of Multiple Function Device Products. So shifting back to the premarket context, to summarize the overarching policy of the guidance, we've just gone over the definition of other functions showing here again on the right. And these other functions are not the subjects of FDA's reviews simply because they're part of a multiple function device product. That is, if FDA is conducting a premarket review of

a multiple function device product and that product contains a function that is not a device, we do not review that non-device function. However, we can assess the impact of these other functions when we are conducting that premarket review.

So for example, a software based multiple function device products which could be a general purpose computing platform itself is not regulated by FDA. However, FDA may assess its impacts on the safety and effectiveness of a mobile medical apps that is a device that runs on that computing platform.

Hardware example is a product that includes an intragastric balloon subject to PMA and an endoscope accessory that is 510(k) exempt like a guide wire. FDA may assess the impacts of the endoscopic accessory on the safety and effectiveness of the intragastric balloon. Next.

So next this guidance describes what this means in practice and what should be documented in a premarket submission. First, manufacturer should conduct a risk assessment to determine if the other functions impacts the safety and effectiveness of the device function under review. Those other functions may have positive effects that enhance the safety and effectiveness of the device function or they may have adverse effects that adversely affects performance and could negatively impact the device functions under review.

Manufacture should include information related to these other functions and their premarket submissions only if the positive effects are represented in the device's labeling: what we call a labeled positive impact. Or if the other function could negatively impact the device function under review. Next.

Now that we've covered the overall premarket policies for multiple function device products, we'll talk about some considerations for multiple function device products. Next.

An important consideration of these products is separation in the design and implementation of the device function under review from the other function. This could be accomplished through logical separation, architectural separation, code and data partitioning.

Making these architecture decisions early in the design cycle and facilitate option separation and support separation that is necessary for the appropriate risk control. Documenting the results of a thorough risk analysis of the impact of other functions and mitigation strategies employed is a critical component of a risk management process.

When separation is not achievable, the interconnection and interdependencies between the device function under review and other function should be explained and included in the hazard analysis, and appropriate control should be created to reduce the adverse impact of the connectivity on the safety and effectiveness of the device function under review.

The higher the degree of separation, the easier it is to independently review the safety and effectiveness of the device function under review. And separation will also increase the likelihood that the device function under review did not it is not dependent on the other functions in the product. This separation is especially important when considering cyber security risk and mitigations. Next.

There are few considerations in a manufacturer of a multiple function device product to keep in mind regarding the impacts of other functions. The role of that other function in the device function under review's performance and the limitations of the device function under review when using the other function. The manufacture should develop appropriate resource specification to ensure there's minimal impact in the other functions and they should consider what the actions the end user may take when using these functions.

And finally, the manufacture should identify, evaluate, and mitigate any additional risk that results in the combination of the other functions with the device function under review. Next.

Next, we'll discuss how FDA may assess the impacts of the other function on the device function under review. Next. Section 6 of the guidance includes a flow chart reproduce here with color to guide this assessment. And later we'll walk through a few examples with the flow chart. Next.

To boil it down a little further, this assessment is summarized in a two-step process. First we ask, is there an impact on the safety or effectiveness of the device function under review as a result of other function. And if there is an impact, could the impact result in an increase risk or have an adverse effect on performance of the device function under review. What we call a negative impact.

For positive impacts, the manufacture should identify the beneficial impact of other function has on the device function under review when operating as intended and confirm that there is no adverse impact on the device function under review if the other function would have failed to operate as intended.

For negative impacts, the manufacture should identify whether there could be increase risk or an adverse effect on performance due to the combination of the other function with the device function under review.

For examples of multiple function and software device products and explanations of the assessment of how other function impact the device functions impact the device function under review, please see Appendix 1 in the guidance. Next.

When assessing the impact of other functions on -- on the device function under review, it's important to consider the various relationships between the functions that may exist in a multiple function device products.

The existence of a relationship does not necessarily mean that there may be an impact on the safety or effectiveness of the device function under review. For example, a software device function such as mobile medical application has a relationship with the computing platform on which it is executed. The computing platform may or may not have an impact on the safety or effectiveness of the software device function.

Here are a few examples of the questions to consider when answering the first question which is, is there an impact on the safety and effectiveness of the device function under review as a result of the other function. I'll note that

this is not a comprehensive list and there may be other questions manufacturers should ask themselves when conducting the risk assessment.

To answer this question, we consider whether the other function provides critical input data that is used for the device function under review or if the device function under review relies on the result from other function. We also consider whether the other function may affect the memory requirements or processing time that's important for the performance of the device function under review.

So once we've thought through these considerations and if the answer to the question, is there an impact, is no, then the manufacture should document this impact assessment and the justification for their determination. If the answer is yes, we proceed to determine the extent of the impacts with the next question. Next slide.

So to determine the extent of the impacts, we consider whether the impact could result an increase risk or have an adverse effect on performance. We can break down the second question to two parts, the possible impacts to safety and the possible impact to effectiveness. The impacts of safety are often impacts associated with risk.

For example the other function could introduce a new hazardous situation or increase the severity of harm associated with the hazardous situation. The other function could be a risk control measure or it could impact a risk control measure for the device function under review. Next.

The impacts to effectiveness are typically impacts to the performance of the device. For example, impacts to the responsiveness, usability or efficiency of the device. For example, the performance or clinical functionality of the device function under review depends on the other function for the device function under review to perform as specified. Or the performance of the device function under review fails to meet the specified performance levels due to the other function. Next.

So next, we'll discuss recommendations for content of a premarket submission for a device function under review. Next slide.

As described in 21 CFR 820.30(g), a manufacturer must establish and maintain procedures for validating its device design. This validation includes software validation and risk analysis. And for multiple function device products, manufacturers should include an impact assessment that describes the information we've just reviewed in order to document the manufacturer's determination of the impact of the other function. Next slide.

This slide details what documentation should be included in the premarket submission for a device function under review. If the other function is determined to have an adverse impact or if the sponsor would like to include a positive impact of the other function on the device function under review, then the premarket submission should include the information in this table.

If the other function does not impact the device function under review, then the premarket submission does not need to include this information. However, I'll note that the labeling for the device function under review should include a description of the other function, adequate to ensure the appropriate use of the device.

So let's talk through this table. Indications for use does not need to include the other function unless the sponsor wants FDA to consider a positive impact with the other function. The device description should include how the other function adversely impacts the device function under review or how a labeled positive impact could positively impact the device function under review.

As I mentioned, the labeling should always include the description of the other function adequate to ensure appropriate use of the device and that's even if the sponsor determines there's no impact to the safety or effectiveness of the device function under review.

The architecture and design documentation should explain how the other function interacts with the device function under review and the hazard

analysis should describe the results of the risk based assessment of these impacts.

The requirements and specifications should describe the relationship and interoperability of the device function under review with the other function and the performance testing results should demonstrate that the impacts of safety and effectiveness are addressed. Next slide.

The guidance also describes what assessment should be made if there is a modification to the other function of a multiple function device product. In essence, this assessment should follow the modifications policy for devices which is that if the change could significantly impact the safety or effectiveness of the device function that was a subject of FDA review then you should reference the appropriate modifications guidance seen on this slide to help determine if a new premarket submission is necessary. Next slide.

Although this guidance mostly focuses on premarket review of multiple function device products. It does include a short section on the applicablity of other device and post market requirements. General control requirements apply to device function subject to 510(k), PMA, De Novo, or HDE requirements and those are that 510(k) exempts.

For example, device functions must comply with design control requirements. Another example is that -- that if there were an adverse events for multiple function device products and the manufacturer is aware of information that the device function may have caused or contributed to a death or serious injury then the manufacturer -- then the manufacturer should investigate the cause of that adverse event and submit an AER.

This guidance doesn’t change any other requirements for combination products. Combination product that include multiple function device products have additional requirements such as those requirements applicable to the drug or biologic constituent part. Next slide.

Finally, we're going to use this flowchart to walk through a couple examples from the guidance. Next slide. We'll start with the first example on page 18

of the guidance. This is a smartphone app that detects skin cancer from photos of suspicious lesions of moles.

In this example the device function under review is the software app that detects skin cancer. And the other functions are the smartphone computing platform and the camera on computing platform. In answering the question -- the first question of the flowchart, we determined that the software app depends on the smartphone camera for the photos and depends on the computing platform for the analysis.

Next. So we answer yes to the first question and proceed to the next question. Next slide.

We are asking whether that impact could result in an increased risk or have an adverse effect on performance. And the software app depends on the smartphone camera so the photos depends on a computing platform for the analysis. The output of the camera may not be adequate for detecting skin cancer and photos of sufficient lesions of moles resulting in this diagnosis.

And the smartphones computing platform performance may not be adequate for the software functions including the algorithm intended to detect skin cancer and photos of suspicious legions of moles.

So we answer yes and determine that we need to -- next slide. While waiting for the next slide to get there. Yes.

So we need to include appropriate documentation and the submission to the documents that impact assessment and the determination we have reached. So there needs to be documentation in the premarket submission demonstrating that the increase risk or adverse effects that could result in the combination of functions is mitigated. And we'd expect that documents testing outcomes that demonstrate that there are adequate computing resources including screen size and resolution and error handling to accommodate the common computing platform including that the built-in camera provides adequate images.

We expect the sponsor to document description of specific features with adequate testing outcomes that mitigate risk from software being used on a smartphone or an inadequate camera. So we expect documentation of the specifications to the use of the app with the camera and the computing platform.

To sponsor should document that impact assessment and justification for their determiniation regarding the adverse impact of the other functions in accordance with their quality system.

And finally in this example, the smartphone platform and the camera are not evaluated as part of the premarket review. So the testing outcomes of the device functions under review's performance related to using a smartphone and the camera are evaluated. Next slide.

The next example is on page 23 of the guidance about an energy delivering aesthetic device with an optional app that transfers treatment parameter data for cloud-based storage for later review by a physician. In this example, the device function under review is an energy delivering aesthetic device. And the other functions are the mobile app that integrates the device and transfers treatment parameter data to a cloud-based storage system, and we know there's no real time transmission for this other function and another other function is smartphone computing platform again.

In answering the first question, we determine that the energy delivering device function is not impacted by the mobile app that transfers data or the smartphone computing platform because the transmission of data cannot occur during the energy delivery. Next.

So we answer no the first question. Then next, and the flow chart leads us to the document this impact assessment and justify the no impact determination. We do not need to include documentation in the premarket submission to discuss any increase risk or adverse effect because we determine that there is none. And the sponsor documents the impact assessment and the justification for the determination regarding no impact of the other functions in accordance with their quality system.

And finally the mobile app in the smartphone platform are not evaluated as part of the premarket review and note that again, no documentation of those other functions is necessary for the premarket submission of the device function under review. Next.

The final example we'll discuss today is the pulsed ultrasound and biopsy needle guide kit which is on page 24, the last page of the guidance. This is an ultrasound pulse echo imaging system with software-based biopsy needle tracking functionality that needs to determine the depth or location of the tissue interfaces for use with the biopsy needle guide kit for delivery.

In this example, the device function under review is the general purpose diagnostic ultrasound system and the biopsy needle tracking functionality. The other function in this case is the 510(k) exempt biopsy needle guide kit.

In answering the first question, we determine that the biopsy needle guide kit is a convenience tray that combines a number of other ultrasound accessories that have already received 510(k) clearance or are Class I 510(k) exempt. And the components of the kit are intended to aid with biopsy acquisition specifically the biopsy needle tracking functionality that is guided via ultrasound imagery.

The biopsy needle tracking function should be compatible with the biopsy needle guide kit. So we answer yes to the first question. Next.

And next one more time. So we move to the second question. And we understand that the biopsy needle tracking software may not be compatible with all ultrasound needle biopsy kits. Incompatibility may lead to inaccurate or imprecise guiding of the needle to the target area. Next. So we answer yes to the second question. Next.

And we determine that we need to include documentation in the premarket submission demonstrating that the increased risk or adverse effect is mitigated. We'd expect that sort of biopsy needle tracking software intended to be compatible with various ultrasound needle biopsy kits that performance

testing should be provided showing that the accuracy and precision meet the specifications and requirements of the subject device.

The impact assessment and justification regarding potential adverse impact of the other function should be documented in accordance with the quality system and the sponsors should document that any further processing of the kit in the component does not significantly affect the safety or effectiveness of any of the components under quality systems.

Again, the biopsy needle guide kit itself is not evaluated as part of the premarket review process. So the safety and effectiveness demonstration of the device function under review related to the compatibility of the biopsy needle tracking software with the biopsy needle guide kit is evaluated. Next.

That concludes what we intended to cover today. In summary FDA recognizes that our regulation plays a crucial role in the development of technologies that could significantly impact everyday life. We believe that our approach to regulating these products should foster innovation while protecting public health. The guidance is aimed at clarifying our policy for all multiple function products that contain at least one device function. And the final guidance incorporates feedback from public comments to clarify and provide examples to describe our policy on products with multiple functions.

We hope this guidance provides clarity for manufacturers, FDA staff and other stakeholders on the medical software provisions of 21st Century Cures Act. And this is all part of FDA's long term Digital Health Innovation Action Plan. Next.

I'll point you to the web link for the multiple function device products guidance online. And if you have any questions regarding digital health policies such as if you'd like help determining if your product would be considered a multiple function device, you can reach out to us at digitalhealth@fda.hhs.gov. Next.

If you have any general questions you can always reach out to the Division of Industry and Consumer Education or DICE at dice@fda.hhs.gov. The slides

and transcript and recording of this webinar will be available online in the next couple of weeks. And I'll pause now to assemble the questions.

Coordinator: If you would like to ask a question please press star then one. Unmute your phone and record your name clearly when prompted. If you'd like to withdraw your question, press star two.

Sonja Fulmer: While we're waiting for the questions to come in, I'll go ahead and introduce my colleagues who are also on the line to help answer the questions today. I'm joined by Cathy Bahr, who's the Senior Adviser in the Division of Digital Health. Linh Lo who's the Regulator Adviser in the Office of Product Evaluation and Quality or OPEQ and Aneesh Deoras who is an Electrical Engineer and team lead in the Division of Cardiovascular Devices in OPEQ. Do we have any questions ready for us?

Coordinator: The first question is from (Alexander Walsh). Your line is now open.

(Alexander Walsh): Hi. So the question I had was the guidance document describes how manufacturers should consider the impact of an other function on the safety or effectiveness of a device function under review. But it doesn't seem to address the opposite case where the effectiveness of an other function might potentially be impacted by a device function under review.

If there's a chance that the effectiveness of an other function such as 510(k) exempt function could be affected by device function under review, would that change the status of the other function to turn it into a device function under review?

Sonja Fulmer: I think that that question is ...

(Alexander Walsh): I can give an example if that's not clear.

Sonja Fulmer: I think I understand. But it's -- if I'm missing the mark please let me know.

(Alexander Walsh): Okay.

Sonja Fulmer: I think the 510(k) exempt function, if the combination of it with the device function under review impacts its safety and effectiveness and there's a

significant impact then you should consider the modification guidances that are linked on the slides and that are available as links from the multiple functions guidance as well to determine if there's any change to that function that would require a 510(k).

(Alexander Walsh): Okay. But if the -- for the 510(k) exempt function, if there was a modification and some like to the 510(k) exempt function, that might not need to be addressed by that same flowchart?

Sonja Fulmer: I think it would be outside of the scope of the flowchart. I think you would have to consider the limitations of the exemption for that function. And if a modification to it changes whether or not it's still within the exemption and if it would need its own 510(k). And I think that might be better answered through the modifications guidance.

(Alexander Walsh): Right. Okay. Thank you.

Sonja Fulmer: Aneesh, did you want to jump in there?

Aneesh Deoras: No. That makes perfect sense and I think that's the appropriate way to go. There's certain changes that are relevant to 510(k) exempt devices and excuse me, certain discussions on 510(k) exempt functions in the guidance document. Definitely would recommend checking that out particularly on page four.

(Alexander Walsh): Good. Thank you.

Coordinator: The next question is from (Samehedan Mohen). Your line is now open.

(Samehedan Mohen): Hi. So if there is a system and we decide that and the manufacturers decides that this could be a multiple function device, that a few functions are medical device and a few functions of non-medical device. Is there a way for us to what this decision out with FDA? Could we do like a pre-sub or a 513(g) to make sure that our decision is correct and FDA is aligned with it?

Sonja Fulmer: Yes, absolutely. Particularly if you have questions about whether or not any of those functions are actually non-device functions or if any of them are meeting our new policies we've expressed forenforcement discretion. That's

something that you can do as part of the 513(g), and pre-submissions may also help you understand how we would expect those other functions to impact the device function under review. So I think that's a good place to have that discussion with FDA.

(Samehedan Mohen): Thank you very much.

Coordinator: The next question is from (Dean Papadopoulos). Your line is now open.

(Dean Papadopoulos): Yes. Good morning everyone. Question around how I interpret this guidance, multiple function device product guidance in conjunction with the policy for device software functions and mobile medical applications guidance. Is there a succinct way of describing the difference between those two documents in terms of how they -- how they should be applied in the 510(k) submission process?

Sonja Fulmer: Well, I think that guidance, what we've traditionally called the mobile medical applications guidance or MMA guidance really helped everybody understand what types of functions meets the definition of device, what types of functions, if they meet the definition of device that are low risk. And so we describe our intent not to enforce compliance with applicable regulatory controls, what we call under enforcement discretion.

And then also those that are the focus of our oversight. And so if you have a multiple function device product that has, you know, any number of those types of functions together in one product, it'd be helpful to use the multiple functions guidance to help you understand how some of that other functions, the ones that are non-device functions or the ones that are under enforcement discretion may impact the safety and (attachments) of the device function under review. So the devices that are listed in MMA guidance as being the focus of our oversight, you would want to understand how the other functions could impact those.

(Dean Papadopoulos): Okay. All right. That's helpful. Thank you.

Coordinator: The next question is from (Jeff Bowen). Your line is now open.

(Jeff Bowen): Thank you. I had a question that kind of ties to this and a lot of the more recent guidances that have to do with expanding devices for telemedicine application. So the addition of video conferencing functionality to devices so that healthcare professionals can communicate with each other across distances to either guide the other to operate the medical device to acquire the data and then have screen mirroring functions. So it appears as though a lot of those -- that type of device functionality would already be exempt or defined as another function as described by this guidance.

But it appeared as though the -- those guidance's for expanding that type of capability interpreted to not be the case. And I was just wondering if there was some clarification on that that could be provided.

Sonja Fulmer: Can you clarify what you mean by not be the case?

(Jeff Bowen): So, yes, it seemed that instead of referencing this guidance to remind people that those types of functions are non-device functions. And that companies could implement or utilize video conferencing technology with their systems without the need to submit an additional premarket submission.

It simply stated that they would be under enforcement discretion or that they would not object to the addition of these types of functions. So that's what I mean because it appears as though that one in public health emergency. And that it would be enforced when in fact it shouldn't because of what's outlined in this guidance that you just described.

Sonja Fulmer: So I think that's for the functions that are in our MMA guidance for example as non-device functions like some of the video conferencing examples. I think those -- those will always be non-device function. And I think that the multiple function policy that we've described here in this guidance applies in those cases when there is a combination between those functions and the device function, whatever it maybe.

I'll have to take a closer look at the example you're describing and you're welcome to reach out more directly to digitalhealth@fda.hss.gov to get more clarity on that.

(Jeff Bowen): Thank you very much.

Coordinator: The next question is from (Alison Komiyama). Your line is now open.

(Alison Komiyama): Hi. Thanks so much for hosting this webinar. For a product that has already undergone non-significant risk clinical testing with its multiple other functions including a mobile app that controls those other functions. How does FDA recommend that we demonstrate that the other functions truly do not impact the medical device function namely its effectiveness? Would a risk assessment included in the premarket submission be acceptable in this case?

Sonja Fulmer: Just to clarify. Did you say that there is a function that's controlling the medical device?

(Alison Komiyama): The medical device is not being controlled by mobile app or the other function. There's multiple functions going on with this device. But it's -- in the clinical study everything was run at the same time. So it's hard to parse out just the sole medical device function. If anything, the other functions may have a positive impact. But how do we best explain that to FDA?

Sonja Fulmer: I think that if you look through the guidance and consider the questions that we recommend to help understand how the impact -- how there maybe an impact on the multiple or excuse me, on the device function under review, you can follow those questions, understand what we would expect you think about and -- and what we would expect to see in the premarket submission on it. If there is a positive impact and that's something that you would like to claim, you want to have it labeled is important. Then you would want to include the information in the premarket submission that we went over in the one table.

(Alison Komiyama): Okay. Thank you.

Aneesh Deoras: Hi. This is Aneesh on the line. I think you also had a question about the content of your premarket submission so Section 7 in the guidance document discusses that in more detail and beyond the hazard analysis so your risk assessment. There are other aspects that can help describe your argument for the impact of the other function on the medical device function such as

explaining the architecture of your device, your software requirements and the testing conducted on your device. So there's some helpful information there.

(Alison Komiyama): Okay. Yes, I guess the biggest thing we're trying to avoid is running a whole new 1,000 subject clinical trial.

Aneesh Deoras: Sure.

(Alison Komiyama): And that yes, so the biggest thing, it's hard to parse these things out. But so we think we have a strong argument on why those other multiple functions aren't making an impact or if anything is a positive impact. It's just hard -- yes, it's just that we want to make sure we're making a stronger case. So thank you very much. That's helpful.

Coordinator: I'm showing no further questions at this time.

Irene Aihie: Thank you. This is Irene. We appreciate your participation and thoughtful questions. Today's presentation and transcript will be made available on the CDRH learn webpage at www.fda.gov/training/cdrhlearn by Friday September 18.

If you have additional questions about today's presentation please use the contact information provided at the end of the slide presentation. As always we appreciate your feedback following the conclusion of today's live webinar. Please complete a short 13-question survey about your FDA CDRH webinar experience.

The survey can be found at www.fda.gov/cdrhwebinar immediately and following the conclusion of today's live webinar. Again thank you for participating and this concludes today's webinar.

Coordinator: This concludes today's conference. All participants may disconnect at this time.

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