

**Final Guidance on Medical Device Accessories: Describing Accessories and Classification
Pathway for New Accessory Types
Moderator: Irene Aihie
February 2, 2017
1:00 pm ET**

Coordinator: Welcome, and thank you for standing by. At this time all lines are in listen-only mode for the duration of today's presentation. This conference is being recorded. If you have any objections you may disconnect at this time. Today's conference will feature a question and answer session. If you'd like to ask a question, please press star 1. Now we'll turn the call over to our facilitator for today, Miss Irene Aihie. Ma'am, 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 December 30, 2016, the FDA issued the final guidance on medical device accessories, describing accessories and classification pathways for new accessory types. This guidance document is intended to provide recommendations to industry about the regulation of accessories to medical devices.

It recommends classifying accessories according to the level of risk when used as intended with a parent device to ensure their safety and effectiveness while reducing burden to manufacturers. The guidance also provides clarifications on the definition of a medical device accessory.

Today's presenter is Dr. Erica Takai, assistant director for guidance management here in the Centers for Devices and Radiological Health. Following the presentation, we'll open the line for your questions related to topics in the final guidance only. Additionally, there are other (unintelligible)

subject matter experts available to assist with the Q and A portion of our webinar. Now, I give you Erica.

Erica Takai: Good afternoon, my name is Erica Takai, I'm the assistant director for guidance management for the Center for Devices and Radiological Health, and today I'll be given an overview on our recently issued final guidance on medical device accessories.

So for the agenda for today's webinar I will be giving a highlight on the key takeaways from this guidance, an overview of the accessory's guidance including the background on the guidance, the scope of the guidance as well as the classification policy regarding accessories, key definitions within the guidance and how to apply the accessories' policy and as mentioned earlier, we'll have a Q and A session at the end.

So the key takeaways from this guidance are that FDA is taking a risk-based approach to classifying accessories when used as intended with the parent device. So this means that new types of accessories can be of a lower classification than the parent device, and we encourage manufacturers to use the de novo process to request risk-base classification of new types of accessories. And I'll note here that this policy and the guidance is consistent with the recent 21st Century Cures Act. The guidance also provides clarification on the definition of a medical device accessory.

So for some background on the accessories guidance, the draft guidance was issued January 20 of 2015. We received ten sets of comments and there were no significant policy changes that resulted from the comments we received. I'll note here that we did make some clarification changes to the guidance, including some clarification regarding how this applies to software as a

medical device, or SaMD. And the final guidance was then published December 30 of 2016.

So what is the scope of the guidance? This guidance is only applicable to devices defined under Section 2018 of the Food, Drug and Cosmetics Act, and therefore also for software as a medical device or SaMD, this guidance is applicable to the SaMD that meets the definition of a device under the Act. We also focus in this guidance on the use of the de novo classification process to classify accessories of a new type.

So we've received a number of questions and comments about, what about existing accessories. So similar to any other device, existing accessories can still be classified under 513(e) and 513(f)(3) of the act, and the principles and the guidance apply to these existing accessories when they're undergoing reclassification. And the reason for this is because through the medical device user fee amendment user fee negotiation, we along with industry have committed to working together to identifying appropriate reclassification pathways for existing Class III accessories. So this is still a work in progress.

So historically how have we been regulating accessories? Historically accessories have been included automatically into the same classification as the parent device, and this may happen through 510(k) pre-market notification clearance of the accessory being found substantially equivalent to another accessory or to another 510(k) cleared device, or through pre-market application approval or through the explicit inclusion in the classification regulation or reclassification order for the parent device.

I'll note here that we do have some classification regulations that are split regulations, where the parent device is already a different, higher classification than the accessory. The other way is, the other way that

accessories have been classified is through the issuance of a unique, separate classification regulation for the accessory itself.

So our approach moving forward is a risk-based classification of accessories. Now on December 13 of 2016, Section 513(b) of the Food, Drug and Cosmetics Act was amended by 21st Century Cures to state that the secretary shall classify an accessory based on the intended use of the accessory, notwithstanding the classification of any other device with which such accessory is intended to be used and the guidance is consistent with 21st Century Cures.

So what does this mean, a risk-based classification of accessories? This means that the classification of accessories should reflect the risks of the accessory device when used as intended with the parent device. So some accessories may have a lower risk profile than the parent device, and these may be appropriate to be regulated in a lower class than the parent device. In other cases, some accessories can have the same risk profile as the parent device, and in these cases it would be appropriate to regulate these accessories in the same classification as the parent device.

So now for some key definitions in the guidance. Accessory is defined in the guidance as the finished device that is intended to support, supplement and/or augment the performance of one or more parent devices. Finished device as defined in 21 CFR 820 is any device or accessory to any device that is suitable for use or capable of functioning whether or not it is packaged, labeled or sterilized.

We define a parent device in the guidance as a finished device whose performance is supported, supplemented and or augmented by one or more accessories. A component as defined in 21 CFR 820 is any raw material,

substance, piece, part, software, firmware, labeling or assembly which is intended to be included as part of the finished package and labeled device.

I'll note here that earlier this week, on January 30, we updated the, we made a minor update to the accessories guidance to remove an imprecise statement regarding the definition of a finished device.

So how do we apply the accessories classification policy? So we apply the policy by asking two key questions, which are, "Is the device an accessory?" and then we have some sub questions to help us answer that. Then we ask, "What are the risks of the accessory when used as intended with the parent device or devices, and what regulatory controls are necessary to provide a reasonable assurance of its safety and effectiveness?"

So now when we look at the first question, "Is the device an accessory?" and ask the first sub-question, "Is the device intended for use with one or more parent devices?" we determine the answer to this question by looking at the labeling for the potential accessory device and not the parent device. Keep in mind here that articles used with the device that are not finished devices are not accessories. For example, off-the-shelf computer monitors or peripherals would not be accessories. So just because an article is packaged together with the device doesn't automatically make it an accessory.

So if the answer to that first Part A question was yes, we move on to the next sub-question, which is, "Is the device intended to support, supplement, and/or augment the performance of one or more parent devices?" So we're going to split this up into support, supplement and augment. So we ask, does the device support the performance of a parent device by enabling or facilitating that device to perform according to its intended use?

So examples of this include a tunneling tool for use with the neurostimulator to enable proper lead placement so that the neurostimulator can stimulate the intended target tissue.

Another example is an infusion pump stand, where the infusion pump stand is holding up the infusion pump at a comfortable height for a health care provider to use the pump. So the next sub-part to this question is supplements. So does the accessory or, sorry, does the device supplement the performance of a parent device by adding a new function or a new way of using the parent device without changing the intended use of the parent device?

Some examples of this is a new delivery system that expands the patient population in which the parent device can be used. More specifically, it could be a trans-catheter valve, a new delivery system for a trans-catheter valve that would allow the valve to be placed in patients with smaller anatomy.

Another example would be input devices such as thermometer, such as a thermometer or a pulse oximeter to a multi-parameter monitor, which would allow the multi-parameter monitor to display more types of physiologic parameters.

So the last subpart to this question is augment. Does the device augment the performance of a parent device by enabling the device to perform its intended use more safely or effectively? An example of this includes bone cutting guides to assist in the positioning of total hip or knee arthroplasty components, or a color or contrast filter to enhance the raw images generated from the parent imaging device.

Please keep in mind that the differences between support, supplement and augment may be subtle, and as long as the device is doing one or more of

these things we would consider the answer to this question to be yes. So if the answer to parts A and B were yes, then the answer to the question “Is the device an accessory?” would be yes.

So I’d like to provide some additional clarity regarding software as a medical device at this point. Through our collaborations with the International Medical Device Regulators Forum we have defined software as a medical device as software intended to be used for one or more medical purposes that performed these purposes without being part of a hardware medical device.

So software or SaMD that meets the definition of a device under the Act similar to other stand-alone devices are classified according to their risk. The other point I want to note is that SaMDs using data from another device don’t automatically become an accessory if they are not considered to support, supplement, and/or augment the performance of a parent device.

So the example for this is a stand-alone software program that is intended to analyze radiological images is not considered an accessory. So SaMDs are considered an accessory when they’re used in combination, for example as a module with other devices and support, supplements and/or augments the performance of these parent devices. So the takeaway here is the accessories policy applies to software as long as they meet the definition of an accessory.

So I’d like to now give an example of how we think through whether or not something is an accessory by using the example of a pulse oximeter. A stand-alone pulse oximeter that’s not intended to be used with the parent device and is not intended to support, supplement or augment a parent device would not be an accessory.

On the other hand, a pulse oximeter that's intended to be used with a multi-parameter monitor, therefore to be used with the parent device, and as intended to supplement the multi-parameter monitor to display oxygen saturation without changing the intended use of the multi-parameter monitor would be considered an accessory to the multi-parameter monitor.

So once we establish that a device is an accessory, then we move on to the next question to assess the risk of the accessory when used with the parent device and what the necessary regulatory controls are to ensure safety and effectiveness.

So the first subpart of this question is we ask, "Is it a new type of accessory?" The answer to this question is yes if the accessory has not been classified by an existing classification regulation, and it has not been cleared in any 510(k), and it has not been approved in any PMA. Now note that any new intended use for an already cleared or approved accessory may be considered a new type of accessory. So if you're not sure whether or not your device is a new type of accessory, you can contact the appropriate review division for further consultation.

So also, if you find that your accessory is not a new type of accessory the current options are to request a reclassification under 513(e) or 513(f)(3).

So if your accessory is a new type of accessory, then you would assess the eligibility for classification into Class I or Class II using the de novo process. So to assess this, we ask "Does the accessory pose low to moderate risk to health?" and we also ask "Can general controls, or special and general controls provide a reasonable assurance of safety and effectiveness?" And if the answer to these questions is yes, then your device, or your accessory may be eligible for de novo.

So I want to reiterate the key takeaway messages again. So in this guidance, FDA is stating that we are taking a risk-based approach to classifying accessories when used as intended with the parent device. So this means that new types of accessories can be a lower classification than the parent device, and we encourage manufacturers to use the de novo process to request a risk-based classification for new types of accessories. And accessory guidance provides clarification on the definition of medical device accessories.

So for additional information on device determination, you can refer to our device advice page on this particular topic. If you're not sure if your device is a new type of accessory, you should contact the relevant review division. If you have questions about, related to SaMD, please e-mail the digital health mailbox and for general inquiries, you can contact our Division of Industry and Consumer Education through this e-mail address.

So for our panel Q-and-A discussion, I'm going to introduce our panelists. We have Angie Krueger, who's our acting deputy director in the Office of Device Evaluation, and we have Scott McFarland, he is an associate director in the Office of In Vitro Diagnostics and Radiological Health. We have Bakul Patel, he is our associate director for digital health, and Joni Foy, our acting associate director for policy and myself. We'll now take questions. Operator, are you there?

Coordinator: Yes, if you'd like to ask a question, please press star 1. To withdraw your question, you may press star 2. Once again, if you'd like to ask a question, please press star 1. You will be prompted to record your name. Please do so clearly at the prompt. One moment while we wait for the incoming questions. Our first question is from (Anderson Giraldo). Your line is open.

(Anderson Giraldo): Hello, how are you?

Erica Takai: Great.

(Anderson Giraldo): Hi, so we develop orthopedic implants. And we have instruments which we consider accessories. However, they are system-specific, they're specific to our implants. So no one else can use them. Can they be classified under Class 1 devices?

Joni Foy: Joni Foy, so for orthopedics, you know, you've mentioned that the product is specific to be used with the parent product. So in this situation and since you've indicated that it's part of the system, this would fall under this guidance document. If you're wanting to separate out the instruments from the parent based upon the risk, you should consider submitting a de novo.

There is a separate classification for manual orthopedic instruments that is intended for general instruments, and those are Class I. So just to clarify, if you were really intending yours to be a specific instrument that's used specifically with your implants, then a potential option would be a de novo.

(Anderson Giraldo): I'm sorry, it's just that the connection is not very good; I could only hear half of it. So I guess is it a Class 1 device, or not?

Joni Foy: I'm not going to repeat everything, can you hear me?

(Anderson Giraldo): Yeah, now it's a little better, I'm sorry. But I couldn't hear you before.

Joni Foy: That's okay, sorry; I may not have been close enough to the microphone. So you know, if this is the situation where you have a specific instrument that is used specifically with an implantation type system, it sounds like this, you

know, guidance would actually encourage you to come in for a de novo classification process.

There is a separate classification regulation for manual surgical instruments when the instrument in and of itself is not intended to be used with a specific system. One sort of caution which I didn't mention before for those that may have been able to hear me previously was that if you've already gotten clearance for your product, you know, this utilization of a de novo pathway is not the appropriate pathway for you to utilize. So I don't know the specifics of your situation and if you do have specific questions for your particular situation, I would refer you to the division of orthopedic devices...

(Anderson Giraldo): Yes, so actually we did receive prior clearance. They've already been cleared. But now...

Joni Foy: You're in a situation where, especially if it went through the 510(k) process, your product has already been classified through that mechanism, and so this is not what this guidance document focuses on. We already have existing classification or reclassification processes for those that Erica mentioned as part of the presentation through either 513(e) or through 513(f)(3).

(Anderson Giraldo): Okay, thank you very much, appreciate it.

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

(Lugene Birach): Hi, this is (Lugene Birach), I have a question about accessories and classification in the GUDID database. Do accessories have to be entered into the GUDID database, and if so do they use the 510(k) number for the medical device for which it's an accessory?

Erica Takai: So for UDI inquiries, we recommend that you contact the UDI help desk because there may be complexities in your case that we wouldn't be able to answer in an accurate manner in a case-by-case situation. So we recommend that you ask this question to the UDI help desk with the specifics of your specific case.

(Lugene Birach): Okay, thank you.

Woman: We'll take our next question.

Coordinator: The next question is from (Joseph Chmieliski). Your line is open.

(Joseph Chmieliski): Hi, everyone, I hope you're having a great day. We have a Class II 510(k) nuclear medical device, already cleared, and we're looking to make actually, relatively substantial design changes and as a result submitting a new 510(k). As part of the design changes we're introducing, the design change of the parent device, introducing additional, okay I guess optional components or accessories to that that will be, the labeling will be directed in the parent device.

Is the agency still accepting based on 510(k) submission for a system where we're looking for significant changes to the parent device in addition to identifying and showing substantial equivalence for, you know the accessories or other components contained within that?

Erica Takai: Yeah, so this guidance wouldn't change the way of how you can come in with the pre-market submission, you can still come in as a system. So whether it be an accessory or stand-alone device as part of a system with another device, you can still just come in with one 510(k) for the whole system.

(Joseph Chmieliski): And then just utilizing the parent classification for the whole system?

Erica Takai: So if you are choosing to say that, if your particular accessory is not a new type of accessory or even if it is a new type of accessory, if you believe that it should be in the same classification of the parent device, then you know you put it in with your parent device and when we clear it it'll be in the same classification as your parent device.

(Joseph Chmieliski): Thank you very much.

Coordinator: The next question is from (Ben Curson). Your line is open.

(Ben Curson): Hi, thank you, good afternoon. First off, thank you very much for the presentation and the opportunity to ask some questions. My question is around existing accessories that are supplementing and/or augmenting performance of the parent device, where the parent device actually has multiple classifications.

So depending on its intended use and how it's used in the field it could either be Class 2 or Class 3, that accessory is included in both of those submissions. Is FDA taking a risk-based approach with those types of accessories as well, where the manufacturer would be able to justify that the accessory would take on a lower classification, or does it automatically take on the highest classification of the parent device for which it's intended to be used?

Erica Takai: So ...

Scott McFarland: I think in that situation it would be risk-based. You're indicating it for such a purpose. Like if you represent that one of them is very high risk, and we'd

have to consider that in how we end up classifying the accessory. My understanding is, was this an already classified accessory?

(Ben Curson): Yes, so...

Scott McFarland: If it's already been classified, then it wouldn't change unless you were coming in via reclassification mechanism, as Joni indicated, which would be either 513(e), which is most likely the case, or 513(f)(3) if it was a post-amendments device that was approved in a PMA.

(Ben Curson): Right, and in this instance we would have first had clearance through 510(k) for the parent device as well as the accessories for, in this example it's a fixed-bearing knee, I guess would be a great way. But the femoral component can also be used in a rotating platform application, which is Class 3. The accessory can be used in either one, and does that automatically make it a class three accessory, or can we make it a rationale as to why it really has the same risk classification as the Class 2 device?

Erica Takai: So it's based on the risk of the accessory when used as intended with the parent device. So if we determine that the risk of the accessory when used with that Class 3 indication is Class 3 type of risk, then it would still be appropriate to be in Class 3. So you have to base it on the risk of the accessory when used with the parent device as intended.

(Ben Curson): Okay, thank you.

Coordinator: Our next question is from (Richard Tucker), your line is open

(Richard Tucker): Ah, thank you for the opportunity to ask a question. My question is primarily rooted in some things that I learned having conducted, recently finished a risk-

based work inspection assignment addressing orthopedic manual surgical instrument devices. And my assignment was assigned to be conducted at a contract manufacturer, a pure contract manufacturer; they don't make any finished devices of their own.

The example that I'd like to use for my question are torque-limiting drivers, including screwdrivers and these torque-limiting driver devices that can be used with interchangeable instrument tips, so to speak. Clearly these do support and augment finished devices; I'll use the example of drivers that are being used during C-spine and/or spinal orthopedic surgeries. And typically and historically these drivers have been identified as Class 1.

The root of my question is, now that we know that that's going to change, how does, how does the contract manufacturer come into play here? Because frequently they just simply receive a specification from the original equipment manufacturer, and they're not specifying classification and they're not indicating, there's currently, and this is common practice across the industry, there is no indication of who if anybody is responsible for design control if that class one device will now be reclassified into either Class 2 or Class 3.

Angie Krueger: This is Angie Krueger, acting as deputy director in ODE.

(Richard Tucker): I'm sorry, I can't hear.

Angie Krueger: Okay, sorry, can you hear me now?

(Richard Tucker): It's slightly better.

Angie Krueger: Okay, this is Angie Krueger, acting as deputy director in ODE. It sounds like the specific devices that you're talking about here, at least to the orthopedic

accessories, are already classified in Class 1. And so this guidance, the final accessories guidance, doesn't change the paradigm and the class for this product.

(Richard Tucker): That conflicts with the assignment information that I've been given. It's clearly indicated within the scope of the assignment that these accessories would in fact take on the classification of the finished device, which might be the implant or the implant kit when and if use of that accessory is in any way included in the IFUs, or referenced in the IFUs.

Angie Krueger: So I think in the particular example that you're bringing up it sounds very specific to specific regulations and specific issues that it sounds like we'd have to work through, and I think that may be better for that question to be coordinated through, the division here, in ODE if it's ortho, orthopedic-related. We could certainly send you appropriate contact information if you don't know who to contact.

(Richard Tucker): I would much appreciate that, and I would also venture to say that those contract manufacturers that are in this industry of supporting orthopedic surgical implants, there's a huge question here. And we're looking at tens of thousands of MDRs over the last couple of years and ten deaths, and everybody's pointing the finger at everybody else indicating that they're not responsible for design control.

Angie Krueger: So I think at this point I'd encourage you to reach out to DICE, their e-mail address is dice@fda.hhs.gov, and they'd be happy to route your question to the appropriate folks within the agency.

(Richard Tucker): Thank you.

Angie Krueger: Thank you.

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

(Chadra Moray): Hi, yeah, thank you for taking my question. This is also a pretty specific question but I would try to make it as generic as possible. One of the mechanisms to classify the accessory is that we have been using traditionally, its 21 CFR descriptions of the products. So for example, for endoscope accessories, the endoscopes are mostly classified as Class 2, while the accessories such as cleaning brushes and the walls are classified as Class 1 clearly under the endoscope regulations.

However, when we have a very traditionally based, other accessories which go along with the Class 2 parent device, there is not a clear regulation on 21 CFR, so we have been doing that, as the agencies guide, based on the risk of the accessory. One of those accessories is a jet wallet, which basically is used to (unintelligible) the backflow, and in a recent guidance document that was issued by agency on the irrigation system validation, it seemed that not only the jet water channel but as well as the air water channel and the forcep channel are part of the irrigation system, and the agency's requesting to provide appropriate validation data for it.

That sort of changes the classification status for other accessories which have been traditionally classified as Class 1, and we were wondering if we have to reclassify the accessories which are being affected by that particular guidance, as well as are there any specific channel that we can use for the accessories which hasn't been mentioned in the endoscope regulation.

Erica Takai: So thank you for your question. So I do want to reiterate that this guidance doesn't change the classification of accessories that have already been

classified in a classification regulation or have already been cleared in a 510(k) already. So, whatever classification your accessory is in now is what it will continue to be in unless you come in with a reclassification petition. But if you want to have further discussion on your particular topic, then you should come in and you could contact DICE and we would route internally to the right review division.

(Chadra Moray): Okay, that sounds great, thank you.

Coordinator: The next question is from (Dan O'Leary). Your line is open.

(Dan O'Leary): Hi, the draft guidance document included batteries as accessories rather than components, especially in an example of a battery in an automated external defibrillator. This isn't in the final guidance, so what is the current view on batteries and the role of accessories?

Erica Takai: So we took that example out because we thought it may be ambiguous, the differences between accessories and components. So I will say that if the battery is part of the original defibrillator, we do consider those to be a component.

(Dan O'Leary): Okay, great, thank you.

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

(Charles Sing): Hi, I have a question regarding using of a commercially available, like a PDA or mobile devices, and how would you classify this if I wanted to include it as part of the instrument?

Bakul Patel: This is Bakul Patel. Can you just repeat the last part; you said you wanted to include the mobile devices...

(Charles Sing): As part of an instrument. A medical device.

Bakul Patel: Your question is what part of it, you're wondering, is an accessory?

(Charles Sing): If the commercially available device should be submitted and classified as part, when it comes with the software.

Bakul Patel: Let me see if I can again repeat this back to you and see if I got your question right. Are you wondering if there's a product that you're considering and wanting to use a off-the-shelf, mobile platform that they're pretty much an computer in the product, how would that be considered?

(Charles Sing): Right and we are designing software to run on it. And that may be part of a larger instrument that we consider a parent device.

Bakul Patel: Yeah, so in this case what we are calling, what we've said in the past is computing platforms are not necessarily classified as part of the product that you're making, so it is part of the product and how you control the risk of that and how you think about it as a system, as a product itself, is what you should think about. This may not be something that this guidance really applies to this particular example that you're bringing up.

(Charles Sing): Okay, so it wouldn't really be considered as an accessory.

Bakul Patel: Would not be considered as an accessory, but it would be the product, the component of the product itself. The entire product.

(Charles Sing): Okay, thank you.

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

(Charles Agbanah): Thank you for taking my call. My question is regarding embedded software. Let's say you got an approval on embedded software in a system, and then you decide to upgrade the software for the system to do couple of other things, from what you said basically the embedded software is not an SaMD, am I correct?

Bakul Patel: This is Bakul again, I think in your example, the purest example was talking about a mobile phone being part of a testing product or some sort of in vitro product. In that case, the mobile platform itself is part of the IVD or whatever product that the gentleman was talking about.

In your case, what you're referring to is software that is driving the hardware product, for example if it's an infusion pump or some other product that has an embedded piece of software in it. To me that is not software as a medical device as defined by the international Medical device regulators forum (IMDRF) and what we adopted as international regulatory forum in what we call SaMDs. SaMDs are those that are purely products stand-alone software that can run on its own and fulfill a medical purpose on its own. It isn't required to drive, control or anything else, it's just about computing data and providing some things that is meant for a medical purpose.

(Charles Agrabah): Thank you.

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

(Jan Zorn): Thank you very much. I actually have two questions. My first is if there is a component in the flow path of a durable medical piece of equipment, and that component is replaceable by the user, does that require any additional separate filing?

Erica Takai: So without details of the particular case, we really couldn't answer this particular question. For questions asking about specific cases, I would recommend that you route your questions through DICE, because we're not going to be able to give a regulatory response to specific cases in this Q-and-A session.

(Jan Zorn): So perhaps the answer to my second question, that is if you have a cartridge that is designed to introduce a specific chemical into the flow path of a durable piece of medical equipment for the purposes of disinfection, strictly disinfection, is that considered an accessory?

Erica Takai: Again, you know, it really depends on the specifics of your particular device, so we're not able to provide an answer to that question. We do recommend you come in and ask; send your question to DICE so we can have a conversation with you about your specific case.

(Jan Zorn): Okay, thank you.

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

(John Williams): Thank you and I appreciate the opportunity to ask this question. We have an approved medical device for which we have an approved accessory. We want to add another accessory, and we know that for this additional accessory, that we have a predicate device and we have a reference device, namely that we have a reference device which operates by the same mechanism but doesn't

have the same indication. But I would like to ask you is, is it your recommendation that we pursue either a 510(k) pathway to gain approval, or that we pursue the de novo pathway?

Erica Takai: So if you already have a predicate device, then a 510(k) would be the appropriate pathway.

(John Williams): Okay, but this predicate device, even though it has the same indication, it has a different mechanism.

Joni Foy: So right, this is Joni Foy, just to clarify, you know, 510(k)'s appropriate if you have a predicate that also translates into having the same intended use and the technological characteristics don't raise different questions of safety and effectiveness.

(John Williams): Okay, so if I...

Jonie Foy: Seems like you may have been going with the second clarification.

(John Williams): Okay, thank you.

Coordinator: Our next question is from (Westev Banyati), your line is open.

(Westev Banyati): Hi, this is (Westev Banyati) and thank you for taking my question. I have an exempt device, a (unintelligible) device, sorry, that is, has a software, but we need a monitor, it's an interactive monitor that in order for us to run the software and it has a stand. Would the monitor be considered an accessory in this case?

Bakul Patel: This is Bakul again. I mean, general purpose products are not something that we're considering as accessories, at least for this discussion today.

(Westev Banyati): Even though we need that particular accessory in order for the software to, you know, to be abused to the client, to the patient, right?

Bakul Patel: If that's one of the requirements for your product, that's something you should consider how you're controlling whatever things you need to have your product meet the intended use.

(Westev Banyati): Okay, thank you.

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

(Carol Gonzalez): Thank you so much, I appreciate the opportunity. This is in reference to web-based or cloud-based software uses support a service activity or a workflow, to support a medical device activity, but the software is not directly connected to the medical device. My question is whether that particular software is considered, should be considered an accessory to the medical device or not.

Bakul Patel: So first of all let me bring your attention to the definition of software as a medical device. I think what Erica had pointed out earlier was, and I'm not quite understanding the utility of the cloud-based software that you just mentioned in association with the medical device, but just because you're using a technology or a platform that is just touching a medical device does not make it an accessory.

That was the point of software as a medical device, just like if pulse oximeter being used with a multi-parameter monitor is an accessory, but pulse oximeter

by itself can also be a medical device. Software as a medical device should be used in the same concept.

(Carol Gonzales): Okay, so for example, this particular service or functionality supports some sort of a service activity or business activity required to support the medical device. So for example, it will be transferring the images or DICOM images from one location to another, and so in a way it supports the service or functionality of the medical device, so.

Bakul Patel: Yeah, so I think you may be referring to what we used to define as medical device data systems, as defined in the current regulations as products that transfer, store, display or convert from one format to another, the medical device data. And that's really if you're referring to that, and that's not something that we are enforcing right now and under 21st Century Cures that provision, that definition is not a medical device.

(Carol Gonzales): Okay, okay, perfect. And because actually the regulation says or the guidelines say that if you're not connected to the medical device, perhaps you're not an accessory, so that wasn't clear. And the other question I have is in reference to health IT and the involvement with the medical device. So there is no clarity other than a guidance for mobile applications to the implementation of systems that can support again the medical device. So are there any plans...

Bakul Patel: So, may I just interject for a second. I think we may be off topic here for a second. The topic of health IT and the work that we're doing, that should be directed somewhere else. This seminar today we are discussing our final policy on accessories. So appreciate your point but if you want to write to FDA, you should contact digitalhealth@fda.hhs.gov, and we can get back to you or consider your input as we look through these issues.

(Carol Gonzales): Thank you.

Coordinator: Our next question is from (Yayo Fujimaki), your line is open.

(Yayo Fujimaki): Hello, so....

Coordinator: Yes, your line is open.

(Yayo Fujimaki): Okay, thank you. So we make orthopedic implants and implant-specific instruments as well as general orthopedic instruments. And before, several years before, we classified orthopedic implant specific or original as a Class 1. However, in recent 510k submissions, we are encouraged to include device-specific instruments. So we consider the implants and the specific instruments overall Class 2. However, after this guidance came, I have two questions.

So can such implant-specific instrument, manual instrument be considered as Class 1 because the risk level is similar to general orthopedic instruments, and the second question, if that is yes, does FDA continuously expect us to include implant-specific Class 1 instrument in 510(k)?

Joni Foy: This is Joni Foy again, so we've already answered a similar question regarding this earlier. You know, currently the way that they have been done is they have been cleared through the 510(k) if it's specific for utilization with insertion or implantation in the orthopedic implant, so they've been technically classified as Class 2. If it's a generic type of instrument, that is classified under our Class 1 regulation. Don't have the regulation number right in front of me, but manual orthopedic surgical instruments that are generic have been classified as a Class 1.

This is the third question we've received on orthopedic instruments, so it sounds like we may want to have additional internal dialogue regarding this particular matter so we can provide some additional clarification going forward. But as we've also articulated, we're not changing the classification of products that have already been classified or have a specific classification regulation through issuance of this guidance.

(Yayo Fujimaki): Okay, I understand, thank you.

Joni Foy: Thank you.

Coordinator: Our last question comes from (Carly Desmond), your line is open.

(Carly Desmond): Hi, so I have a question about product labeling. We're the manufacturers of an electronic instrument that is intended to read rapid diagnostic tests. We don't actually manufacture any rapid diagnostic tests, our goal would be, to be able to list in our labeling which particular tests we're compatible with, and then to register with the FDA as appropriate as a system.

My question is, does the labeling of the parent device need to mention our device, or is it only through our labeling that we're defined as an accessory?

Man: So I think, it sounds like that'd be a pretty device-specific question. I'd definitely recommend that you submit it to the DICE e-mail that Erica's mentioned a few times so we can look at the specifics.

(Carly Desmond): Okay, thank you very much.

Coordinator: We now conclude our question and answer session, thank you.

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 Learns webpage at www.fda.gov/training/cdrhlearns, by Friday, February 10. If you have additional questions about the final guidance document, please use the contact information provided at the end of the slide presentation. As always, we do appreciate your feedback.

Please complete a short survey related to today's webinar. The survey can be found at www.fda.gov/cdrhwebinar. Again, thank you for participating, this concludes today's webinar.

Coordinator: Thank you for your participation in today's conference, all participants may disconnect at this time.

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