Final Guidance: Remanufacturing of Medical Devices
September 10, 2024

Moderator: CDR Kim Piermatteo

CDR Kim Piermatteo: Hello everyone, and welcome to today's CDRH webinar. Thank you for joining us. This is Commander 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's webinar.

Today we would like to discuss with you the final guidance titled Remanufacturing of Medical Devices, which was issued on May 10, 2024. The purpose of this guidance is to clarify the distinction between servicing and remanufacturing of medical devices to help ensure consistency and a better understanding of the regulatory requirements applicable to remanufacturers.

I'd now like to introduce our presenter for today's webinar, Dr. Frances Wilder, Regulatory Advisor on the Regulation, Policy, and Guidance Staff within CDRH's Office of Product Evaluation and Quality, or OPEQ. We'll begin with a presentation from Frances and then field your questions about our topic.

Before I turn it over to Frances, I'd like to provide a few reminders. First, please make sure you've joined us through the Zoom app and not through a web browser to avoid technical issues. Second, the intended audience for this webinar is industry. Trade press reporters are encouraged to consult with the CDRH trade press team at cdrhtradepress@fda.hhs.gov. And members of national media may consult with FDA's Office of Media Affairs at fdaoma@fda.hhs.gov. Third, printable slides of today's presentation are currently available on CDRH Learn at www.fda.gov/training/cdrhlearn under the section titled Postmarket Activities and the subsection titled General Policy. And lastly, we look forward to interacting with you during the live question and answer segment of today's webinar. If you have a question, please wait, and raise your hand at the end of today's presentation to get into the queue.

Thank you all again for joining us. I'll now turn it over to Frances to start today's presentation.

Frances Wilder: Thanks, Kim. Here is the link to that final guidance for anyone who wishes to access on their own.

For today's presentation, I will walk through the remanufacturing final guidance. I will discuss why we're issuing guidance on this topic and the scope of the final guidance. Additionally, I will explain how we're proposing that entities analyze their activities and determine whether they are likely remanufacturing through the use of the guiding principles and other relevant considerations. I'll also talk about the existing regulatory requirements that are applicable to remanufacturers. Finally, I'll discuss the information that should be included by original equipment manufacturers in their own device labeling to facilitate servicing and ensure the continued safety and performance of reusable devices.

For many years now, FDA has been working to gain additional perspectives on the distinction between servicing and remanufacturing of medical devices and has undertaken several efforts to help promote clarity between these activities. Our efforts include a docket and public workshop in 2016 to gather public feedback regarding servicing and remanufacturing of medical devices. In 2017, in accordance with the FDA Reauthorization Act of 2017, we were charged by Congress to publish a report on our findings from the workshop and our planned actions for addressing the issues surrounding servicing and

remanufacturing. The report was published in May 2018, which concluded in part that a majority of the comments, complaints, and adverse event reports received by FDA that refer to inadequate servicing are actually related to remanufacturing of medical devices.

It should be noted that the distinction between whether an entity is servicing or remanufacturing is important because it affects the applicability and enforcement of regulatory requirements by FDA. And FDA has consistently enforced requirements on entities engaged in remanufacturing.

In 2018, we also released a white paper, opened another public docket, and held another workshop to facilitate discussion on how to distinguish between servicing and remanufacturing. After considering feedback at the workshop and public comments received to the docket, we published a draft guidance on remanufacturing of medical devices in 2021. Then in May of this year we published the final guidance, which is the focus of today's webinar.

The intent of this remanufacturing guidance is to clarify the distinction between servicing and remanufacturing activities, with a focus specifically on activities that are likely remanufacturing, which has certain regulatory implications. This guidance is not intended to adopt significant policy changes from what the agency has been doing, but to simply clarify and explain FDA's current thinking on this topic, including the relevant definitions and the existing regulatory requirements that are applicable to remanufacturers.

The products included within the scope of this guidance are devices as defined in section 201(h) of the FD&C Act, including software and electronic products that meet the definition of a device. In general, the concepts discussed in this guidance are meant to apply to all reusable devices, irrespective of their device classification. However, this guidance is not intended to address reprocessed single use devices which have their own policy associated with them.

Next, we'll walk through some key definitions provided in the guidance. The definition of a remanufacturer is actually spelled out in our regulation in 21 CFR 820.3(w). Remanufacture is defined as any activity that processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's intended use or performance specifications or safety specifications.

In contrast, service is defined as the repair and/or preventative or routine maintenance of one or more parts in a finished device for purposes of returning it to the safety and performance specifications established by the original equipment manufacturer, or OEM, and to meet its original intended use. So, servicing specifically excludes activities that significantly change the finished device's safety or performance specifications or intended use.

We recognize that within the medical device ecosystem, there are many stakeholders, each of which may perform different activities across different devices. Broadly speaking, there are manufacturers, which include OEMs, and remanufactures, and then there are servicers, which include third party servicers and independent service organizations.

The designations of manufacturer and servicer are not mutually exclusive. An entity may meet multiple definitions based on the activities it performs on one or multiple devices. For example, an entity could be both an OEM that manufactures its own device and a third party servicer that services another

entity's device. So as far as FDA is concerned, in terms of enforcement of regulatory requirements, we focus on the specific activities an entity performs on a particular device, regardless of that entity's self-identified designation as a servicer or remanufacture.

With these definitions in mind, we'll now discuss how an entity should assess whether the activities they perform are remanufacturing. The guidance lays out six guiding principles that should be considered to help make that determination. First, one should assess whether there is a change to the intended use of the device. Given that the purpose of servicing is to return the device to meet its original intended use, any change to the intended use of a device should be evaluated and may likely be remanufacturing.

Second, as specified in the definition for remanufacture, one should determine whether an activity significantly changes the safety or performance specifications of a device. It is important to note that FDA considers changes to also include any improvements or enhancements made to the device, and when multiple changes are made at the same time to a device, it is important to assess these changes, both individually and cumulatively, as there could be compounding effects.

For the third guiding principle, one should evaluate whether any changes to a device would require a new marketing submission. This is an assessment that should be made regardless of whether the activity is remanufacturing, and there are applicable regulations that apply to you when marketing submissions are required and of course, there are FDA guidance documents that one could consult with to make that determination.

Number four, one should assess the impact of component parts or material changes by comparing the specifications to the OEM device. This assessment can be comparative and/or through verification and validation testing. Deviations in these specifications can be significant and may require a closer evaluation, such as through engineering analysis or a risk-based assessment. For changes related to component part or material, we have also developed a flowchart to help guide these assessments, which I will explain in the next few slides.

For guiding principle five, we recommend entities employ a risk-based approach. An activity is likely remanufacturing when a risk-based assessment identifies any new risks or significant modifications to known risks, as these are likely to significantly change performance or safety specifications in comparison to the legally marketed device.

And last but not least, for guiding principle six, we recommend entities to adequately document their rationale for the determination of whether an activity is remanufacturing.

With these guiding principles in mind, now let's dive a bit deeper. Just as a reminder, by definition, remanufacturing is an activity that significantly changes a finished device's intended use performance or safety specifications. During our 2018 workshop, there was a lot of discussion about what constitutes a significant change, which we tried to clarify in this guidance and provide examples.

First, any change to the intended use of a device should be carefully assessed not only for its implications related to remanufacturing, but also with respect to whether a new marketing authorization may be required. Some examples of what we consider to be significant changes to intended use include but are not limited to changing a single use device to become reusable or changing the anatomical location of use for the device.

For device performance or safety specifications, we consider a significant change to be one that, based on verification and validation testing and a risk-based assessment, to result in a finished device that is outside the OEMs performance or safety specifications, or introduces new risks or significantly modifies existing risks.

Additionally, we have also provided example activities in the guidance that, in general, we believe would significantly change a device's performance or safety specifications, and therefore, would likely be remanufacturing. These include changes to the device's sterilization methods, reprocessing instructions or changes to a device's control, mechanism, operating principle, or energy type.

To help further assess certain activities involving changing components, parts, and materials, we created a flowchart for this guidance and recommend using the flowchart with its accompanying text in the guidance to help assess whether those activities are likely remanufacturing. However, it is important to note that the flowchart should not be used to assess any software changes, which I will explain later.

On the right-hand side of the slide shows the full flowchart. The way we have set up this flowchart is that the left side of the flowchart include questions that are objective decisions based on the activities that an entity performs, whereas the right side includes the assessment of the impact of those activities on the performance and safety specifications. We recognize that it is not always necessarily a binary decision between remanufacturing and servicing. There are other activities that an entity could perform on a device. Because in this guidance we're focusing on remanufacturing, the output of the flowchart helps distinguish whether an activity is likely to be remanufacturing.

Now let's go through each set of the flowchart questions. There are three sets of questions in the flowchart, and within each set, as I mentioned, there is an objective decision and followed by an assessment. For question A1, we asked if the activity adds, removes, or changes a component part material that directly or indirectly contacts body tissue. Direct contact is physical contact with body tissue, whereas indirect contact can include fluid or gas passing through a device component prior to that fluid or gas coming into physical contact with body tissue. If there is any uncertainty about this question, then the answer should be yes, and one should proceed to question A1.1.

You'll notice the assessment question is identical throughout the flowchart. It asks, is there a significant change in device performance or safety specifications? Regarding body contact, any change should be assessed for its impact with respect to biocompatibility and reprocessing instructions, which were validated for the legally marketed device. Depending on the magnitude of the change, new reprocessing validation or a comprehensive biocompatibility risk assessment or testing may be necessary. Activities that impact the adequacy of the legally marketed device's validated reprocessing instructions or biocompatibility evaluation are likely remanufacturing. If yes, then the change is likely remanufacturing. If no, one should proceed to the second set of questions.

Question A2 asks whether the activity adds or removes a component, part, material or changes the dimensional or performance specifications of a component, part, material. Any additions or removals should result in a yes to A2, whether it's an adhesive or removing a fastener or barrier or replacing any OEM part with a non-OEM part. This can also include changes to dimensional or performance specifications of a part, component, material. If the answer is yes to these, then we move to the assessment question in A2.1.

For this question, we recommend an analysis that considers the intended use life of the product and how the activity could affect that. For example, the criticality of change dimensions or whether performance outputs will fall outside of the OEM product's minimum or maximum specifications. If yes to this question, then the change is likely remanufacturing. If no, one should proceed to the last set of questions.

Question A3 asks if there is a new or modified risk, or if there is a change in the performance or safety specifications. This question is intended to be a catch all for any remaining activities, obviously with the exception of software, where a risk-based assessment is conducted to identify any new or modified risk or additional changes to performance or safety specifications. If no, the activity is likely not remanufacturing. If yes, one should proceed to A3.1.

For the assessment, any new or modified risks should then be analyzed to see if they significantly change the performance or safety specifications of the finished device. Examples of which include those changes that alter or bypass safety features, affect conformity with a standard, and/or compliance with a regulation. If yes, then the change is likely remanufacturing.

Based on the inherent differences between mechanical and software changes, the flow chart, along with the risk-based assessment approach just described, should not be applied to changes involving software. Software changes can have an impact on a product's software architecture, software requirements specifications, unresolved anomalies, and other key characteristics, which are likely to be significant. Additionally, the probability of a software failure cannot be determined using traditional statistical methods. Because of these reasons, many software changes are likely remanufacturing. However, to help promote clarity, we have identified certain activities performed on software that are likely not remanufacturing.

So here is the list of software activities that we have identified to likely not be remanufacturing, as they generally do not significantly change the performance or safety specifications of the legally marketed device. I won't read through all the examples, but just want to highlight a few, such as implementing certain software updates that are authorized by the OEM or running diagnostics or assessing for cybersecurity related issues. You can refer to the complete list of examples in the guidance.

As I've mentioned, we highly recommend entities to have sufficient documentation for any decision making related to whether activities are remanufacturing, which can facilitate an FDA investigator or another third-party auditor's understanding of what the change was and the rationale underlying the conclusion. Appendix B of the guidance includes examples of what documentation for a remanufacturing assessment may look like. Of course, an entity is welcome to develop their own templates. However, at a minimum, we recommend that the documentation to include the product name, dates, descriptions of the device and the activities performed, whether the activity is remanufacturing and references to related documents supporting that conclusion.

Now that we've covered how an entity should assess for whether activities are remanufacturing, let's discuss the regulatory requirements and considerations for remanufacturers. Under the FD&C Act and FDA's regulations, remanufacturers are considered manufacturers and are thus regulated as such. Entities that remanufacture devices are subject to the same regulatory requirements as the original equipment manufacturers of medical devices.

That means remanufactures must register their establishment and list their remanufactured devices with FDA. They must comply with appropriate premarket authorization requirements such as premarket notification or premarket approval for any remanufactured devices. Remanufacturers must also comply with medical device reporting, reports of corrections and removals, quality system, and labeling regulations for any remanufactured devices.

As we have learned from our various engagements with stakeholders, unintentional remanufacturing may occur when servicing entities do not have the instructions necessary to return a device to its original performance and safety specifications. For reusable devices that require routine preventative maintenance and repair, it is important for such devices to include instructions on how to adequately return the device to its performance and safety specifications established by the OEM. The lack of adequate servicing instructions can create challenges in the continued availability of quality, safe, and effective devices. So consistent with promoting and protecting public health, we highly encourage OEMs as an industry best practice to provide servicing instructions that facilitate routine maintenance and repair of their reusable devices.

This guidance recommends some specific information to be included in the labeling of any reusable devices, which include a description of the key performance and safety specifications, critical technical or functional specifications, the recommended maintenance activities and schedule, recommended routine testing and acceptance criteria, a description of error codes, alerts, and alarm features on the device, precautions and warnings relevant to servicing the device, and version number and release date of any software included in the device.

Now that we've covered the content of this final guidance, for anyone who has been following this guidance since it was published in draft a few years ago, I just want to briefly highlight some of the changes we made in the final guidance. We received many great comments and feedback on the draft guidance, and we've reviewed and considered all of them. While we did not make any substantive changes to the policy itself, we did further clarify a few things.

For example, we added contextual examples of activities to provide further clarity for whether activities are remanufacturing. We clarified the applicability of the guidance to OEMs and external entities acting on behalf of OEMs. We also added a new section to the guidance to further clarify the existing regulatory requirements applicable to remanufacturers.

The guidance concludes with an appendix of illustrative examples of activities that may be performed on devices and analyses of whether these activities are remanufacturing. These examples obviously do not account for every possible details of real-world scenarios but are meant to demonstrate how to implement the policy described in this guidance. I would like to now walk through one example today related to an endoscope. So the lens of an endoscope is cracked. The lens is attached by an epoxy that is not described in the labeling. The entity removed and replaced the cracked lens. The epoxy used was purchased from the OEM and is identical to that used in the legally marketed device. The replacement lens comes from a different endoscope model from the same OEM. That model was 510(k)-cleared with improved optical performance relative to the original endoscope lens. The replacement lens has the same material but different optical specifications from the original legally marketed device.

So, because this example involves changing a device component, we'll use the flowchart and its accompanying text to help us determine whether the activity is likely remanufacturing, starting with question A1. Are we adding, removing, or changing a component part material that directly or indirectly contacts body tissue? The answer is yes. We are replacing the lens and the epoxy, both of which directly contact body tissue. Then that leads us to question A1.1. Is there a significant change to device performance or safety specifications? The epoxy is identical to the epoxy used in the legally marketed device. The replacement lens is the same material as the original lens. Further, a risk-based assessment considering both the individual and cumulative changes determined that the procedure used to replace the lens does not affect the biocompatibility and reprocessing instructions. A biocompatibility assessment also confirms that there are no new surfaces previously unexposed to body tissue. Finally, a comprehensive free processing risk assessment and testing demonstrated that the validated reprocessing instructions are not impacted by the replacement parts, or the procedures used to replace the parts.

So the answer to this question would be no, which leads us to the next question. Question A2 asks if we added or removed component, part, material or changed the dimensional or performance specifications of a component, part, material. The answer would be yes since we replaced the lens with one that is different from the OEM version.

Next, is there a significant change to device performance or safety specifications. The epoxy is identical to that used in the legally marketed device, but the lens has different optical specifications from the original lens. The endoscope with the replacement lens has different imaging specifications relative to the legally marketed device. While the replacement lens is present on another 510(k)-cleared device, it was not present on the original endoscope, and it does significantly change the performance specifications of the original endoscope despite the fact that the change may be an improvement on the original endoscope. So, the answer to this question is yes, which means the activity is likely remanufacturing.

With that concludes my presentation today. To briefly summarize, entities that perform activities on devices should apply the guiding principles and relevant considerations described in this guidance to help assess whether their activities are remanufacturing. If remanufacturing, one should comply with all regulatory requirements that are applicable to device manufacturers, which, by definition, includes remanufacturers. And to mitigate the risk of unintentional remanufacturing, we highly encourage original manufacturers of reusable devices to include adequate servicing instructions in the device labeling.

Here are some of the resources mentioned during the presentation.

Thank you for your attention. I will now turn it back over to Kim.

CDR Kim Piermatteo: Thanks for that informative presentation, Frances. We are now going to transition to our interactive question and answer segment for today's webinar. Before we get started with that, I'd like to introduce two additional panelists who will be joining us for this segment and who will be available to assist with addressing your questions today. Joining us is Katelyn Bittleman, Policy Analyst on the Compliance and Quality Staff within CDRH's Office of Product Evaluation and Quality, or OPEQ. And Angela Krueger, Deputy Office Director for Regulatory Policy in OPEQ. Welcome to you both and thanks for joining us.

Now I'd like to go over how we will manage this segment and a few reminders. To ask a question, please select the Raise Hand icon, which should appear on the bottom of your Zoom screen. I'll announce your name and give you permission to talk. When prompted, please select the blue button to unmute your line and then ask your question. When asking your question, please remember to limit yourself to asking one question only and try to keep it as short as possible. And we appreciate that you may have a very specific question involving your device or scenario, however, we might not be able to answer such specific questions, therefore, we will try to frame a broader response based on what's described in this guidance. After you ask your question, please lower your hand in Zoom, and if you have another question, please raise your hand again in Zoom to get back into the queue and I will call on you as time permits.

So, as you think about and prepare your questions for our panelists, I'd like to ask our additional panelists a few questions that we've previously received regarding this final guidance. So, Katelyn, I'd like to ask you our first question, and that question is, are remanufacturing and servicing the same activity?

Katelyn Bittleman: Thanks, Kim. So this is Katelyn. The short answer is no, they are not the same activity, although they are also not mutually exclusive as well. So as such, servicing alone should not lead to any significant changes to the intended use, performance, or safety specifications of the overall device. So, in the end, if there is no significant change to any of these characteristics, then the activity itself is not likely to be manufacturing.

CDR Kim Piermatteo: Thanks, Katelyn. I'd now like to direct the next question to Angela. Angela, the question is, does FDA believe original equipment manufacturers or OEMs should share instructions, manuals, and other important information with servicers to assure the safety and performance of devices being serviced?

Angela Krueger: Thanks, Kim. FDA always encourages transparency to ensure the continued availability of safe and effective medical devices to patients. While we're not requiring specific labeling information and are certainly not compelling disclosure of trade secrets or confidential commercial information, FDA does recommend that certain device information be included in OEM labeling to facilitate proper servicing of reusable devices, including the routine device maintenance and repair. FDA outlines what we see as the minimum information that should be provided in OEM labeling for reusable devices as an industry best practice.

CDR Kim Piermatteo: Thanks, Angie. OK, so our first live question is coming from Pam. Pam, I have unmuted your line. Please unmute yourself and ask your question.

Pam N.: Hi. We manufacture devices that we sell under our brand, and we also contract manufacture this similar device for OEM as for other company for another manufacturer under their brand name. If we change our device from our brand and change that device into their brand by refurbishing, if we do that, is that considered remanufacturing?

CDR Kim Piermatteo: Thank you, Pam, for that question. Katelyn, would you like to start?

Katelyn Bittleman: Sure. Thank you, Kim. And thank you, Pam, for that question. So I do think that we would need a little bit more information to give you a more specific answer. But in general, if the devices themselves are exactly the same, they're manufactured the same and are cleared under the appropriate, either a 510(k) or whatever the appropriate authorization is, I don't think that changing the branding itself necessarily makes it remanufacturing, because you're not changing the intended use, you're not changing the performance or safety specifications. Not to say that it wouldn't need some other review or things along those lines. And for specific questions along those lines, I would encourage a Pre-Submission questions to be sent to the agency to really nail home the specifics of your situation. But in general, again, we are pretty agnostic to the entity that's actually performing the device, the changes, or the activities themselves. And so if the activities have been cleared or the activities are generally not changing those pieces, I would not consider it remanufacturing, full stop, as far as that's concerned. I'll hand it back to you, or if anyone else wants to add to that answer.

CDR Kim Piermatteo: Thanks, Katelyn. And thank you, Pam, for that question. Our next question is coming from Kalima. Kalima, I have unmuted your line. Please unmute yourself and ask your question.

Kalima Speights: Hi, thank you. Could you please repeat the link for the slides? I didn't get the whole link written down to pull the slides up.

CDR Kim Piermatteo: Oh, Sure. Yeah. So the slides for today's presentation are available on our CDRH events page. So, if you just go to www.fda.gov, in the top right you can click on that search box and type in CDRH events, and then they're organized by date. And so, then you can find it, the remanufacturing webinar for today, and there's a link there to the printable slides.

Kalima Speights: OK, great. Thank you.

CDR Kim Piermatteo: Sure. Alright. Our next question is coming from Brett. Brett, I have unmuted your line. Please unmute yourself and ask your question.

Brett Eckles: OK, great. Can you hear me, OK?

CDR Kim Piermatteo: Yes, we can.

Brett Eckles: OK, great. Thank you. Yeah, so I had a question. We are an OEM manufacturer for our own devices and have capital equipment in the field. So when we have product changes where a hardware or software modification, we assessed that a 510(k) submission was required. We submitted one and had appropriate clearance. When we go to upgrade the existing distributed products to match the 510(k)-cleared version, are those devices remanufactured or was that considered a servicing activity?

CDR Kim Piermatteo: Thank you, Brett, for that question. Katelyn, I'm going to go ahead and turn it over to you, but any of our other panelists, feel free to chime in.

Katelyn Bittleman: Yes, thank you. And thank you, Brett, again, for the question. Oops, sorry. The short answer is, as I'm sure my colleagues will agree, that it depends, right? So, it sounds like there are hardware changes and software changes from one device to another, and again, both are cleared. So, my questions would be to help delineate whether or not the upgrades themselves would be remanufacturing would be, was the, during the clearance process of the secondary 510(k) or the

upgraded 510(k) device, is it considered, are there other components that would be, what's it? critical to the functioning of the device that are dependent on whether those components are brand new manufactured, manufactured brand new, or recycled as far as the retrofitting process of those upgrades. And so, if any of those types of activities for those kinds of upgrades or the retrofitting of the physical upgrades, as you said, not necessarily the software ones, I would still go through those underlying questions of, are any of those activities affecting the process or affecting the overall safety and effectiveness of the device? And so, I hope that answered your question, but I'll open it to Angie and Frances as well if you want to weigh in.

Angela Krueger: Thanks, Katelyn. This is Angela. The only thing I was going to add was that one of the general principles that is outlined in the guidance does focus on this issue regarding whether the change required a new marketing submission and discusses in the context of 510(k) what that would mean. And so, I think regardless of, and I think Katelyn's right, I think it may matter the specifics of the hardware or software changes to determine whether it meets the definition of remanufacturing. If those changes required a 510(k) and you sought 510(k), submitted a 510(k) and sought clearance and received clearance, the likelihood is that you have met your regulatory requirements. So, I'd just take a look at that general principle number three in the guidance to help focus those issues and bring them together.

CDR Kim Piermatteo: Thank you, Katelyn, and thank you, Angela, for your response, and thanks, Brett, for your question.

Brett Eckles: Thank you.

CDR Kim Piermatteo: OK. Our next question is coming from, I apologize, it's Yashaswini. I have unmuted your line. Please unmute yourself and ask your question.

Yashaswini M.: Hi. Thank you. So, my question was like, what is the difference between serving and remanufacturing of medical devices like that?

CDR Kim Piermatteo: I apologize. Could you speak up a little bit more and repeat your question for me, please?

Yashaswini M.: OK. What's the difference between serving and remanufacturing of medical devices? Difference?

CDR Kim Piermatteo: OK. So, your question is basically what is the difference between servicing and remanufacturing, correct?

Yashaswini M.: Yeah. Yeah.

CDR Kim Piermatteo: OK. OK. Katelyn, would you like to take first response?

Katelyn Bittleman: Sure. So yeah, I do think that that's probably the core values of what this guidance is trying to get at. And I would like to just to state that we regulate the remanufacturing processes. It's not necessarily that it's that any activity that someone performs is remanufacturing or servicing. There are other activities that go on that don't meet either of those definitions. And so, what we try to focus on is

whether or not the activity itself is remanufacturing or not, and not necessarily put into that bucket of its servicing, therefore it's not remanufacturing.

But to answer your question a little bit more directly, the main difference are the significant changes, right? If there are significant changes, such as specifically to the performance or safety specifications or the clear and intended uses or authorized intended uses of the device itself, then that would be remanufacturing, and you would have to look at whatever the devices themselves are to see whether or not you would need a new marketing application or meet any of the other regulatory requirements associated with that device.

Yashaswini M.: OK. Got it. Thank you.

CDR Kim Piermatteo: Thank you. And thanks, Katelyn, for your response. Our next question is coming from Dustin. Dustin, I have unmuted your line. Please unmute yourself and ask your question.

Dustin "Monte" Montecillo: Hi, good afternoon. Can everybody hear me?

CDR Kim Piermatteo: Yes, we can.

Dustin "Monte" Montecillo: Hey. So, we are a third-party servicer, and we use non-OEM parts. So as I work through this flowchart, I get to A2 and 2.1. In consideration with non-OEM parts, would there need to be documentation for every non-OEM part that we use for a repair or preventative maintenance? We do, you mentioned earlier that there is, you want to focus on the safety and effectiveness of the device and is there a significant change. I would like to argue that if I use calibrated test equipment to the OEMs work instructions, that there would not be any, but specifically to non-OEM parts, what would the FDA like to see in regard to our risk reporting?

CDR Kim Piermatteo: Thank you, Dustin, for that question. I'm going to turn it over to Frances. Frances, would you like to provide a response?

Frances Wilder: Yeah, sure, happy to. So yeah, as you've mentioned, it's definitely important for you to walk through the flow chart and document your rationale according to the flow chart. For example, comparing the specifications of the non-OEM part against the OEM part, document any differences, potentially, and whether they may or may not be significant. So, it's really important, any testing you do to support that verification or validation, it's important for that to be included in your documentation and as part of your rationale for your assessment.

Dustin "Monte" Montecillo: OK. Thank you for your time.

CDR Kim Piermatteo: Thank you, Dustin, for your question, and thank you, Frances, for your response. Our next question is coming from Mike. Mike, I have unmuted your line. Please unmute yourself and ask your question.

Mike Preto: Hi, can you hear me, OK?

CDR Kim Piermatteo: Yes, we can.

Mike Preto: Great. So, understanding that an establishment that acts as a remanufacturer must register and list, are establishments that act as servicers exempt from registration?

CDR Kim Piermatteo: Thanks, Mike, for that question. I'm going to open it up to our panelists. Katelyn, did you want to start, or any of the panelists want to provide a response?

Katelyn Bittleman: Sure. I'm happy to start the response. And so, at this time, if the entity is solely doing, sorry, servicing activities and not significantly changing the devices, servicers are not required to register and list with the agency for medical devices. They're also not subject to most of the requirements related to manufacturing. That said, it's not about what the entity self-identifies as. It's more about what the activities you are conducting. And so, I think there are, actually, I'll just leave it at that. So at the end of the day, no, servicers are not required to register and list. But I do think it is important that you still evaluate the activities you are performing to make sure that you are not delving into remanufacturing unconsciously or by accident.

CDR Kim Piermatteo: Great.

Mike Preto: Thank you.

CDR Kim Piermatteo: Yeah, thanks, Mike, for your question. Thank you, Katelyn, for the response. Our next question, whoops. Jan, I apologize if you are still on, I accidentally did lower your hand. Could you please raise your hand again and I will call on you as soon as I see your hand raised.

There you go. Perfect. Alright, so the next question is coming from Jan. Jan, I've unmuted your line. Please unmute yourself and ask your question.

Jan, I see that you haven't unmuted your line. Please check to see if you are double muted. There you go.

Jan, I can see that you unmuted your microphone, but we still cannot hear you.

Jan Post: Now it should be OK. Can you hear me well?

CDR Kim Piermatteo: Yes, we can.

Jan Post: OK. My question is, if an OEM has developed an upgrade to an existing product, which was submitted and FDA 510(k)-cleared, and that upgrade that was developed and was added to, let's say the technical file of that original product and being sold as a field upgrade. So if the same OEM takes back, let's say their own product from a customer and applies that upgrade during refurbishment and sells it to another customer, my question is then, if that upgrade, and that upgrade involves, let's say some changes in the product, but everything is released according to the technical file requirements, does that mean that the refurbishment activity where the upgrade is applied, does that mean that that is remanufacturing, or is it still within the service domain?

CDR Kim Piermatteo: Thank you, Jan, for your question. I'm going to turn it over to Angela.

Angela Krueger: Thanks, Kim. I think there's a couple things here, and we'd likely need more information about the specific activities, and I would encourage you to take the specific example and think through the guiding principles and each one of the specific questions that's outlined in the flowchart and the accompanying text. There are a couple of things that lead me to believe that based on how you described is it is likely remanufacturing. I think when you're talking about and use the term upgrade, for example, that, to me, speaks to the fact that it is likely a significant change in the safety or performance specifications. So, I'd look at that closely in the context of the specific activity. I think it's less, for example, about who's distributing based on how you described your example, but I would tie it back and focus on what's actually happening to the device, are those things changing. So, you go through the objective questions in the flowchart and then apply the information on the right to determine whether those changes are significant.

So without more details, I think it's hard to tell, but use of the term upgrade, to me, is probably a little bit of a trigger word and probably would put me more in the remanufacturing camp. And as outlined at the beginning, if you have a specific question and would like our SMEs to evaluate that, feel free to reach out and we'd be happy to answer any specific questions so that you can provide more information about the specific activities. Over to you, Kim.

CDR Kim Piermatteo: Great. Thank you, Angela. And thank you, Jan, for your question. Our next question is coming from, it looks like a company name. It's Verathon, Incorporated. I have unmuted your line. Please unmute yourself and ask your question.

Ash: Hi. So I have a question about software upgrades or changes or updates. There are specifics listed in the guidance, I see, of when it's considered a remanufacturing versus not versus servicing, but it is a limited list. What do you suggest as far as when we're trying to determine situations, parameters outside of that to, I know you say there's a follow the guiding principles, but is there any additional documentation or resources to try to distinguish? I mean because there's no flow chart like there is with the systems.

CDR Kim Piermatteo: Thank you. Can I ask your name?

Ash: Ash.

CDR Kim Piermatteo: Ash. OK. Thank you, Ash. Katelyn, would you like to provide a response to Ash?

Katelyn Bittleman: Sure, I can start, but I just want to make sure I understand the question fully. So, the question is more about what additional resources are there for determining whether the process of the activity is through manufacturing?

Ash: Well, whether software changes, like the criteria listed for software changes, whether or not they hit that threshold or not.

Katelyn Bittleman: Gotcha.

Ash: It's a list and there's not really a flowchart.

Katelyn Bittleman: I understand. Yeah.

Ash: Yeah. Does that make sense?

Katelyn Bittleman: Yes, it does, and thank you for clarifying. I appreciate that.

Ash: Yeah.

Katelyn Bittleman: So yeah, the main reason we ended up having a list of activities we figured were likely servicing when it comes to software changes is because we mostly believe that, in general, changes to software that are not reviewed through a marketing submission are most likely remanufacturing. I'm sure there are specific resources that we can provide if you do send an email to us, whether it be through DICE or the regulations and policies email box, and I'll go ahead and ask Kim to provide any specific contact information. Or you can always submit a Pre-Submission to ask about specifics related to any software changes. But in general, we do think that, and that's why we had listed the activities that we think are most likely servicing, because we do think that it's a much shorter list on that end than it is on, to have that flowchart of all of the software changes that could be considered remanufacturing. I hope that answers your question.

Ash: No, it helps quite a bit. I guess can I ask one clarifying.

Katelyn Bittleman: I'll ask Kim. Is that allowed?

CDR Kim Piermatteo: Yeah, that's allowed. Go ahead.

Ash: OK. I mean, so we don't follow that, does it affect performance and safety?

Katelyn Bittleman: Right.

Ash: OK.

Katelyn Bittleman: Yeah. Yeah, and so that's why we had a hard time as well. And so, the physical changes associated with physical, changing the device in the physical space, are not the same questions of when it comes to software, right? And so I think you're on the right path as far as what questions you're asking and what questions will lead you down the right path. But when it comes to specifics about that, I would encourage you to reach out to us and talk to us and we can have the proper subject matter experts really weigh in.

Ash: Thank you so much.

Katelyn Bittleman: Yeah, of course. Thank you.

CDR Kim Piermatteo: Thank you, Ash, and thank you, Katelyn. OK, so I hope we can get to two more questions today. The next question is coming from, it looks like just an iPhone. So that person, if you could identify yourself and unmute your line, I have given you permission to talk.

Millie: Thank you. Can you hear me?

CDR Kim Piermatteo: Yes, we can.

Millie: OK. I'm Millie. My question is change of the power supply of the device from dry cell battery to rechargeable lithium battery, would that consider a remanufacturing or is just servicing, a servicing?

CDR Kim Piermatteo: Thank you, Millie, for that question. I'm going to open it up to our panelists. Anyone want to jump in?

Frances Wilder: So yeah, I'm happy to start. So, it sounds like this is a change in energy type to the device, which I think we have explicitly stated that that is likely to be remanufacturing in the guidance.

CDR Kim Piermatteo: Great. Thank you, Frances. And thank you, Millie, for that question. Alright. I think we have time for one more question. That question is coming from Levi. Levi, I have unmuted your line. Please unmute yourself and ask your question.

Levi Moore: Great. Thanks. In the guidance, you go through all the list of how to assess whether or not a change is remanufacturing. But in the assessment step, my question is, are qualitative assessments sufficient? I.e., if I get two images and look at them and say, that looks fine to me, is that a sufficient analysis to determine whether or not I have returned something to the OEM specifications?

CDR Kim Piermatteo: Thank you, Levi, for that question. I'm sorry. Go ahead.

Katelyn Bittleman: No, I was going to say I can start us off with an answer. And so unfortunately, the answer is it depends, right? So, if you're looking at a qualitative comparing two pictures or something, that really would require there to be a quantitative assessment of whether or not the range of, there is range of specifications or an output that you're trying to analyze. I would say that, in general, a qualitative assessment is not really sufficient in that sense. But if you're looking at if the specification in and of itself is qualitative, then the answer is maybe, right? And so, I would say that you really should be using the expertise and specificity of the device itself, as well as the activity. If the justification can only be qualitative in that sense and using that risk-based approach that we have outlined in the guiding principles of the guidance, then the answer could be yes. But without specific information about the activity itself, the device itself, and what the changes are, I'm hesitant to give you a firm answer on yes or no.

Levi Moore: Sure. Is there going to be any enforcement around any of this or is this all just to make everybody feel good?

Katelyn Bittleman: So, I do think that enforcement in and of itself is outside of the scope of the guidance itself, but we do have a duty to enforce the rules and regulations that have been set up upon us.

Levi Moore: Thank you.

CDR Kim Piermatteo: Thank you, Levi, for your question, and thank you, Katelyn, for your response.

So that would wrap up our, or that will wrap up our question-and-answer segment for today's webinar. Thank you all for your engaging questions and for interacting with our panelists today.

I'd now like to turn it back over to Frances to provide her final thoughts on today's topic. Frances?

Frances Wilder: Thanks, Kim. Yeah. Hopefully the takeaway today is that we encourage entities to employ a risk-based approach, including making use of the guiding principles and considerations detailed in this guidance to help assess the impact of the activities they perform on devices and to understand the regulatory implications of those activities. Ultimately, all of our recommendations in this guidance, including those related to documentation of activities performed and transparency of OEM's device labeling to facilitate servicing are really grounded in our collective commitment to ensure the continued safety and effectiveness of medical devices for patients. So thank you and back to you, Kim.

CDR Kim Piermatteo: Thanks, Frances, for those final thoughts. And for your information, a recording of today's webinar and a transcript will be posted in the next few weeks to the webinar page, as well as to CDRH Learn under the section titled Postmarket Activities and the subsection titled General Policy. This is also where, as I mentioned earlier, there is a copy of the printable slides for today's presentation. So a screenshot of where you can find these materials in CDRH Learn is provided on the slide for your reference.

If you have additional general questions regarding today's webinar, please feel free to reach out to us in DICE at dice@fda.hhs.gov. And lastly, we hope you're able to join us for a future CDRH webinar, and you can find a listing of all of our upcoming CDRH events, including upcoming webinars, via the link provided on the bottom of this slide at www.fda.gov/cdrhevents.

Thank you all again for joining us. This concludes today's CDRH webinar. Have a nice day.

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