FDA Webinar: Unique Device Identification: Direct Marking of Devices Final Guidance
Moderator: Irene Aihie
November 30, 2017
1:00pm ET

Coordinator: Welcome and thank you for standing by. At this time, all participants are in a listen-only mode until the question and answer portion of the conference. If you would like to ask a question today, please press star followed by 1 on your touchtone phone. You will then be prompted to record your first and last name.

This conference is being recorded. If you have any objections, you may disconnect.

Now I'll turn the call over to your host, Irene Aihie. Thank you.

Irene Aihie: Hello and welcome to today's FDA webinar. I am Irene Aihie of CDRH's Office of Communications and Education. On November 17th, the FDA issued the final guidance Unique Device Identification: Direct Marking of Devices. The purpose of the guidance is to assist industry and FDA staff in understanding the agency's requirements for direct marketing of medical devices for unique device identification purposes.

Today, Christina Savisaar, Regulatory Policy Analyst for the UDI Program here in CDRH will present an overview of the final guidance. Following the

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presentation, we will open the line for your questions related to information provided during the presentation.

Additionally, there are other center subject matter experts here with us today to assist with the Q&A portion of our webinar. Now, I give you Christina.

Christina Savisaar: Good afternoon and welcome. Thank you for joining us this afternoon for this webinar to discuss the final guidance published earlier this month about unique device identification and direct marking of devices.

During this webinar, I'll be providing a brief background on the unique device identification program, outlining the scope of the guidance, and pointing out key changes from the draft version of the guidance to the final version. I'll also be highlighting some of the information in the guidance and then taking questions over the phone from participants.

The Unique Device Identification, or UDI, Final Rule issued on September 24, 2013. It was designed to have a phased rollout with compliance dates based on device risk. The intent of the Unique Device Identification System is to adequately identify devices through distribution and use.

There are a number of Unique Device Identification System requirements. For many devices, adequate identification through distribution and use is accomplished by placing a UDI on the label and on device packages, and by entering data in the Global Unique Device Identification Database, or GUDID, such that product information can be publicly available to all stakeholders.

However, for a subset of devices, in order to facilitate adequate identification, there is another requirement in the regulation -- to directly mark the UDI on

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the device itself in addition to the label and data submission requirements. The guidance document that we are discussing today is focused on this requirement and explains FDA's interpretation of the UDI Direct Marking Regulations.

Direct marking requirements apply to devices intended to be used more than once and intended to be reprocessed before each use. However, the terms "intended to be reprocessed" and "intended to be used more than once" are not defined in the regulations. To assist labelers in implementing UDI, we developed a draft direct marking guidance, which published in 2015 to further assess the suitability of the definitions in the draft guidance.

In the notice of availability, we asked stakeholders to consider two questions while commenting on the guidance. These questions asked whether cleaning alone should be included in the definition of intended to be reprocessed for purposes of UDI direct marking, and if there was a public health benefit to expanding the provisional definition of intended to be reprocessed for purposes of direct marking to include devices that are only cleaned between uses.

We received and considered 17 sets of comments on the draft guidance from external stakeholders. The final guidance document published earlier this month on November 17th.

The guidance applies to devices that are required to be directly marked under 21 CFR 801.45. That is, it applies to devices required to bear a UDI on their label that are also intended to be used more than once, and intended to be reprocessed. It does not apply to implants, which are not required to be directly marked.

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One key change from the draft guidance to the final guidance is the definition of intended to be reprocessed has been narrowed. In the draft guidance, we considered a device that is intended to be cleaned and either sterilized or disinfected before each use to be intended to be reprocessed. In the final guidance, we consider a device intended to be reprocessed only if it is intended to undergo high-level disinfection and/or sterilization before each use or between uses.

This does not include a device intended only to be cleaned between uses on different patients or intended to undergo lower levels of disinfection without subsequent high-level disinfection or sterilization before each use or between uses.

For purposes of the guidance document, high-level disinfection is a lethal process utilizing a sterilant under less that sterilizing conditions. The process kills all forms of microbial life except for large numbers of bacterial spores.

As a practical matter, you cannot disinfect or sterilize a device that is not clean because there needs to be contact between the sterilant and the device. So devices that are intended to undergo high-level disinfection and/or sterilization are intended to be cleaned between uses as well, but a cleaning step is not what differentiates reusable devices that require UDI direct marking from reusable devices that do not.

Another change with the guidance document that there is an enforcement discretion policy in the final guidance that is new since the draft guidance. This pertains to devices that were consigned or loaned to hospitals or other healthcare facilities or with a sales representative in the field pending sale prior to their applicable UDI label compliance date. To the extent that these devices are required to comply with UDI regulatory requirements for labeling,

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direct marking, or date format, FDA does not intend to enforce compliance with such requirements.

The table on this slide shows the phased UDI direct marking compliance dates. The compliance dates for UDI direct marking for life sustaining and life supporting devices and for class three devices were in 2015 and 2016 respectively. The compliance date for UDI direct marking of class two devices that are not implants, life-sustaining, or life-supporting is September 24, 2018.

Please note that there is not a compliance date listed here for implants, which is a category of device that is called out separately in the UDI rule regardless of device class, because there is no direct marking requirement for implants.

Note also that on June 2, 2017 FDA issued a letter expressing our intent not to enforce the September 24, 2020 compliance date for direct marking of class one and unclassified devices until September 24, 2022.

The UDI that is marked on the device should include both the device identifier and production identifier portions of the UDI. By production identifier portion, we mean all the production identifiers on the label.

There are exceptions to this, however. For example, the UDIs of class one devices are not required to include production identifiers. We are also aware that sometimes a production identifier is unknown at the time during the manufacturing process that a device is directly marked. In these situations, we do not intend to enforce the requirement that the UDI directly marked on the device includes that production identifier that was unknown at the time of marking.

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For UDI on the label, 201 CFR 801.20 makes it clear that unless an alternative or exception applies, the UDI on device labels and device packages must be in two forms -- easily readable plain text and Automatic Identification and Data Capture technology, which I will refer to as AIDC. The UDI marking by contrast per US FDA requirements may be in either easily readable plain-text form or AIDC form or both.

In deciding the form or forms of the UDI for direct marking, labelers should consider factors such as technological feasibility, efficiency for the end user and risk of human error.

Just as it is up to the labeler to determine what form or forms of the UDI to directly mark on the device, it is also up to the labeler to determine the method of marking. We do expect-- excuse me, do NOT expect -- the direct mark UDI to last throughout the expected service life of the device, taking into account expected usage and reprocessing according to the instructions of the manufacturer.

The guidance doesn't specify a particular method of direct marking because it would be difficult to account for the wide variety of devices, use conditions, and reprocessing methods. In addition, technological advancements may lead to change in device usage, methods of device marking, and reprocessing procedures.

Some examples of direct marking methods include placing a permanent plaque or sticker that will withstand reprocessing onto the device, etching, laser marking, and radio frequency identification tagging. This is not an exhaustive list.

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Under 21 CFR 830.310(b)(1), the DI portion of the UDI assigned to a version or model must be submitted to GUDID. This requirement is not specific to direct marking. We refer to the DI included in the lowest level of device package that is required to include the full UDI as the primary DI.

If a device is required to be directly marked and the primary DI and the DI of the direct mark UDI are different, you need to indicate this in GUDID and you also need to enter the direct mark DI number. Also, if the device is required to be directly marked but you are applying one of the exceptions listed in 21 CFR 801.45(d), you should indicate in GUDID that the device is subject to direct marking but excepted.

If a device is not required to be directly marked with a UDI, FDA encourages voluntary direct marking, provided that it does not interfere with device safety and effectiveness and voluntary GUDID data submission requirements applicable to UDI direct marking.

Recall that UDI direct marking requirements apply to devices that are intended to be used more than once. The interpretation of intended to be used more than once has not changed from the draft guidance. As explained in the guidance, intended to be used more than once means intended for repeated uses on or by different patients.

If the device is intended to be used more than once on or by the same patient, and not on or by multiple patients, then the device is not required to be directly marked with a UDI. One way to determine what the labeler believes that a device is intended for is to, for example, reference the cleared or approved instructions for use.

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UDI direct marking requirements apply to devices that are intended to be reprocessed. I talked about this earlier when discussing changes from the draft guidance, but it is very important, so it bears repeating. For purposes of UDI direct marking, we consider a device intended to be reprocessed if it is intended to undergo high-level disinfection and/or sterilization before each use or between uses.

Devices that are only intended to be cleaned or to undergo lower levels of disinfection without subsequent high-level disinfection or sterilization before each use or between uses are not required to be directly marked with a UDI.

There are four general exceptions to direct marking provided for in the UDI regulations. There is an exception available when any type of direct marking would interfere with the safety and effectiveness of the device. There is an exception available when the device cannot be marked because it is not technologically feasible.

There is an exception available when the device is a single-use device and is subjected to additional processing and manufacturing for the purposes of an additional single use. And there is an exception available when the device has been previously marked with a UDI under 21 CFR 801.45(a).

There is no reason to submit a 21 CFR 801.55 request for exception from UDI direct marking requirements to the FDA if any exception under 21 CFR 801.45(d) is applicable. However, labelers must take a few basic steps to make use of an exception that is provided under 21 CFR 801.45(d).

First, as specified in 21 CFR 801.45(e) the basis of the decision must be documented in the Design History File. Second, the GUDID record for the

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device should indicate that the device is subject to direct marking but excepted.

The third step only applies to situations in which the exception being taken is based on technological infeasibility. In these situations, the labeler should plan for periodic reconsideration of the applicability of the exception since the threshold for technological infeasibility may change over time with new technology.

We have received questions from labelers regarding documentation requirements for direct marking their class one devices. For class one devices that are not subject to design controls and therefore do not have a design history file, we recommend labelers provide the documentation in the device master record.

Again, to go back, you will not see anywhere on this list where it indicates that any type of submission to FDA is required to make use of an exception under 801.45(d) because a submission to FDA is not required.

The UDI direct mark is first and foremost a UDI. And a UDI has a very particular form. So the name of the company or a part number alone does not meet the requirements under 21 CFR 801.45. Please note that a labeler is not likely to successfully claim that it is technologically infeasible to mark the device because the labeler left too little space for the UDI direct marking after marking the device with non-essential markings.

However, if there is an important piece of information related to safety and effectiveness marked on the device -- for example, a marking that indicates a device material which can be an allergy or sensitivity concern in certain patients -- and if that marking limits the space left for the UDI, a legitimate

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rationale for applying a direct marking exception may be that it adversely affects safety and effectiveness. This is because in the example the only way to mark the UDI would be to remove the important non-UDI marked information about the device material.

21 CFR 801.55 outlines the process for requesting a specific alternative to a UDI requirement, including what information to provide to FDA. The regulations give very specific criteria under which FDA may grant an alternative.

Under 21 CFR 801.55(c), FDA may grant an alternative if we determine that an alternative would provide for more accurate, precise, or rapid device identification than what is required in the regulations. FDA may also grant an alternative if the alternative would better ensure the safety or effectiveness of the device than what is required in the regulations.

This concludes my presentation. And now we're happy to try to answer your questions about the UDI Direct Marking Guidance. If you would rather not ask your question live during the webinar, the contact information for the FDA UDI Help Desk is listed on the slide as well as the contact information for the Division of Industry and Consumer Education.

Coordinator: Thank you, ma'am. If you would like to ask a question, please press star followed by one on your touchtone phone. You will be prompted to record your first and last name. Please unmute your phones before you record. If you decide to withdraw your question, you can press star two and that will withdraw your question. Once again, press star one and record your name at the prompt. I'll go ahead with the first question.

(Shana Harton) your line is open. Ms. (Harton) do you have your mute on?

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(Shana Harton): Sorry. I actually don't have any questions at this time. I didn't mean to register my voice.

Coordinator: Okay. Thank you. One moment. Let me get the next name. (Debbie Schmidt) your line is open. (Debbie Schmidt)? Ms. (Schmidt) if you still have a question, please check your mute button. Sorry, I'm still getting no response from her. One moment. We can get the next name. I'll check back with her. (Adidi) your line is open.

(Adidi): Hi there. Thank you for putting up this great presentation. We had a question regarding the new definition for intended to be reprocessed and we're looking for a little bit more clarification. Could we get some examples of what FDA considers high-level disinfection versus low-level disinfection?

Christina Savisaar: For high-level disinfection, in the labeling you should be able to determine if it's high-level disinfection or low-level disinfection. But the definition I gave the sterilant still leaves behind some bacterial spores is the definition of high-level disinfection.

In general, this applies to devices that contact broken skin or mucus membranes. But if you have questions about whether the reprocessing of your device falls into that category, you can always check with the review division.

(Adidi): Okay. All right. Thank you.

Coordinator: We have a question from (Diane Wayland). Your line is open.

(Diane Wayland): Hi. Thanks for taking my question. I wanted to know if the guidance had specific requirements for standalone software that is a medical device?

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Christina Savisaar: In the proposed rule, the UDI requirements for standalone software were couched as direct marking, but in the final rule, direct marking only applies to devices that are intended to be used more than once and intended to be reprocessed. So standalone software is not in that category. There's a separate regulation that deals with software requirements for UDI.

Coordinator: I was getting a name. Are you ready for the next question?

Christina Savisaar: Yes, we are.

Coordinator: Thank you. (Jennifer Bingaman), your line is open.

(Jennifer Bingaman): Hi. Yes, I had a question. I'm a little confused on the slide where you showed that any inventory that's intended for reprocessing that's already in the hospitals would not need to be marked with a UDI or would need to be marked with a UDI?

Christina Savisaar: If it was consigned or loaned before the UDI label compliance date, FDA does not intend to enforce the requirement that it is direct marked with the UDI.

(Jennifer Bingaman): So when you say consigned, what's your definition of consigned?

Christina Savisaar: Consigned by contract?

(Jennifer Bingaman): I mean, okay. So like for example if a hospital has purchased an instrument, (unintelligible) and they have that inside the hospital. That would still need to be marked with a UDI because it's not loaned or consigned. Correct?

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Christina Savisaar: If it was purchased by the hospital before the UDI compliance date, then it's not required to be direct marked because it was already sold before the compliance date.

(Jennifer Bingaman): Okay. Perfect. Thank you.

Coordinator: (Gary Chemsik), your line is open. You may ask your question.

(Gary Chemsik): Hi. How you doing? Thank you again for the presentation here. My question is related to seeing if there can be any further elaboration or clarification on what is meant for technologically feasible? Is it directly related to the actual physical direct marking on the product?

Or can it also extend out to the use of scanners that are downstream of the labeler, since, you know, there are very small objects out there and although some might try and move around specific pieces of artwork to accommodate for a plain, readable text or a two-dimensional barcode, the visibility may not be human readable to the, you know, naked eye or possibly even needing some special scanners to read something substantially small.

So can the scanners and technologically feasible, does that extend to the supply chain usability of existing scanners in the market?

Christina Savisaar: It's the intent that it is about the feasibility of what can be marked on the device. And although technology may be at a point where what you can mark and what absolutely every hospital can read is not yet aligned, the idea is that you're considering the marking process on the device. Although, you know, what can be read may influence your decision about what form of UDI to put on the device.

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Coordinator: Any further questions, sir?

(Gary Chemsik): No, I think that's all. Thank you.

Coordinator: You're welcome. Next we have (Nasreen Kabani).

(Nasreen Kabani): Hi. I just wanted to find out is there are any certain regulation about fetal dopplers that are used for home? And that would be used just by one person, but it's not to use by different people. So would we need direct printing of the UDI on a fetal doppler?

Christina Savisaar: If it is only intended for use on a single patient, then it would not be required to be direct marked with the UDI.

(Nasrine Kabani): Would not. Okay. Excellent. Okay. And one more question is that do you have a phone number that we can reach you or anybody that can help us if we have any questions? Or is it always through email?

Christina Savisaar: The Division of Industry and Consumer Education does have a phone number, which is on the…

Irene Aihie: You can actually reach them by email at DICE@fda.hhs.gov.

(Nasrine Kabani): Okay. So that's only an email…

Man: It's also…

((Crosstalk))

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(Nasrine Kabani): …but I was wondering if you have a phone number.

Man: Okay. It's also on the website as well.

(Nasrine Kabani): Okay. So if I go to fda.gov/udi and I would find a phone number there?

Man: For DICE? No, if you go to our web page, you can find it there.

(Nasrine Kabani): Okay. There you go. (Unintelligible). Okay.

Man: But we just pulled it up so.

(Anita Rayner): Excuse me. This is (Anita Rayner) with the Office of Surveillance and Biometrics. I just looked it up. The phone number for the Division of Industry and Consumer Education is 1(800)…

(Nasrine Kabani): Yes.

(Anita Rainer): …six three eight…

(Nasrine Kabani): Okay.

(Anita Rainer): …two zero four one.

(Nasrine Kabani): Great.

((Crosstalk))

(Anita Rainer): And if you want to speak to the industry team, you should press 2 after that.

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(Nasrine Kabani): Okay, got it. I appreciate your help so much. Thank you so much.

(Anita Rainer): Thank you.

Coordinator: (Stephanie Salmon) your line is open.

(Stephanie Salmon): Hi there. I was wondering if we need to directly mark our private label medical devices that we make for other companies.

Christina Savisaar: If a device is intended to be used more than once and intended to be reprocessed, it is required to be direct marked. If it's already marked with the UDI, then there's an exception that it would not have to be remarked. So if the original manufacturer's Udi is on the device, a private label distributer would not have to remark it with their own UDI. Is that…

(Stephanie Salmon): Okay.

Christina Savisaar: …what we're saying?

(Stephanie Salmon): That answers it. Thank you.

Coordinator: Thank you. Next, we have (William Buckle). Your line is open.

(William Buckle): Hi. My question's regarding the inventory grandfathering period for devices that are not direct part marked prior to the compliance date. So my understanding is there's a three-year grandfathering period to allow for product without UDI compliant labeling to move through commercial distribution before having to be reworked with compliant labeling.

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But with direct part marking, there seems to be an implied grandfathering period of only one year. And then I was just going to ask given that for most companies, direct part marking is more difficult to achieve than the labeling compliance. Why is there not any additional time granted for the grandfathering of that inventory as far as direct part marketing is concerned?

(Linda Sigg): Hi. This is (Linda Sigg) with the UDI Program. I believe that the three years is applied to all of it. So the three years is applied to the labeling and the three years from the labeling time for the direct mark. We don't give an additional three years after the direct mark, just the one. But it's all part of the same grandfather.

(William Buckle): Right. And then I think my question is just more about given the difficulty of the direct part marking over the labeling compliance as far as implementing this company-wide for a lot of industries I think it's a bigger challenge for people. It seems like there's an extra two years on the compliance side 2018 versus 2016 to get your direct part marking in place.

An example, for class two products. So there's an additional two years granted for the initial implementation but then that grandfathering period is a much shorter window as far as their direct part mark inventory. And the difficulty of reworking that product, potential disruption to the supply chain, and distribution networks, it just seems like there should maybe be a little bit more time on the direct part marking side, more so than on the labeling side.

(Anita Rayner): This is (Anita Rayner) and yes, we hear you. We understand this presents some challenges to industry. Unfortunately, the regulation is pretty clear as it was written and constructed with the idea of trying to balance the burden of implementation and still try to get as efficient implementation [adoption] of UDI out in the field as possible. So we understand it does present a burden to

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you. We are however, dealing with the constraints of the regulation at this point.

(William Buckle): Okay. Thank you.

Coordinator: (Du Desi), your line is open.

(Du Desi): Hello. Thank you for the great presentation. I think a couple of people have asked the question on the single use components of parts that are not intended to be used more than once. We only had one small question and that is if I know based on your feedback that if it's not intended for multiple use, then it does not need the UDI part marking.

But we have an instrument where it goes, you know, there are multiple parts that go in a case. They do get sterilized multiple times, but they get only used once. So once it gets used, it gets thrown away. And the other instruments that are not used do get sterilized again as part of the complete set. But they don't come in contact with the patient in surgery.

So, is there any exception for this unique situation?

Christina Savisaar: Probably to make sure we have all the details right, I would ask you to submit a UDI Help Desk case because it would depend on the specifics. If it's not intended to be used more than once on multiple patients, then it's not required to be direct marked.

(Du Desi): Okay. I understood that. But even if it gets sterilized a couple of times, even though they don't come in contact with patient, that is also falls under the same category of not needing UDI?

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Christina Savisaar: If it's intended to be sterilized, it would need a direct marking.

(Du Desi): Okay. So if it's a sterilized type part then yes, it will need a UDI because it's sterile packed.

Linda Sigg: Well, and it's probably separated from its label. So the only way to convey the UDI would be through direct part mark.

(Du Desi): Okay, understood. That I can clarify my question. Thank you so much.

Coordinator: (Sonya Horta) your line is open. Ms. (Horta) your line is open. You may need to check your mute button, ma'am. (Sonya Horta)?

(Sonya Porter): I think it's (Sonya Porter)? Is that correct?

((Crosstalk))

Coordinator: Okay. My apologies.

(Sonya Porter): That's okay. I have a question regarding the traceability process. So currently we have units on ICU with serial numbers only. And the new one with serial number and UDI number. So from the traceability perspective, would FDA accept serial number traceability? Or it needs to be UDI traceability only? Or both?

Christina Savisaar: I think we're having trouble understanding your question. Are you talking about traceability or the ability to identify as part of quality systems? Because there is no traceability requirement within the UDI regulation.

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(Sonya Porter): The FDA's expecting to have the traceability on every single unit. So for example, if a company has 1,000 units on the field, so we are responsible to know the location of the unit and the current status. So that we have the serial number for that. So if FDA is going to ask me for that, I know where is my unit.

However, we have two different scenarios. One of them we are tracing them with serial number only. In the other scenario, we have a serial number and UDI number. So for example, if FDA will ask me for the location of my 1,000 units, do I have to provide UDI traceability for them, UDI numbers only? Or serial numbers can be acceptable as well?

Anita Rayner: I think it would probably be best so we can get into the details of what type of product you're talking about and the specific requirements you're talking about, it would probably be best if you included that information in a question directly to the help desk so we can get you the right answer.

(Sonya Porter): Okay. Thank you.

Coordinator: Thank you. We'll move on to (Michelle Evans). I'm sorry. I took that out of order. (Franklin), your line is open. I apologize. I could not hear your last name, sir.

(Franklin): Hello.

((Crosstalk))

Coordinator: Do you have a question?

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(Franklin): Yes. I was wondering how is the UDI regulation and that movement interacting with the GS1 in the development of like a (unintelligible) or a UPC or what - I guess how does the FDA envision that playing out for the facility to track with that UDI?

Anita Rayner: Are you talking about healthcare facility?

(Franklin): Yes.

Anita Rayner: That's sort of outside the scope of this discussion today where we're talking about the requirements on labelers to directly mark their devices. But if you've got a particular question, please send it into the UDI help desk at the address at the top of the screen.

(Franklin): I guess what I'm asking is is the FDA working with the GS1 Organization?

Anita Rayner: GS1 is one of the FDA accredited issuing agencies that we work with and that companies work with to create their UDIs. So yes, we do work with GS1 in terms of them setting up the standards and working with companies to properly construct UDIs for devices. They're one of three accredited issuing agencies.

(Franklin): Okay. Just trying to understand how it all works.

Anita Rayner: Sure.

Coordinator: Any further questions, sir?

(Franklin): No.

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Coordinator: All right, thank you. Now we have (Michelle Evans). Your line is open.

(Michelle Evans): Good afternoon. Thank you very much for the webinar. My question was already answered though.

Coordinator: Thank you.

Anita Rayner: We like these kinds of questions.

(Michelle Evans): Yes, I figured.

Coordinator: If anyone else needs to withdraw their question at this point, star 2 will withdraw. And next we have (Shantel Harper). Your line is open.

(Shantel Harper): Hello. My question is related to application identifiers. It's our understanding that all devices directly marked with a UDI are expected to include the application identifier.

My question is if space does not allow for the additional eight characters and the parentheses and the two-digit identifier, is it acceptable to eliminate the application identifier in order to at least get the GTIN or the DI and the PI directly marked on the device? Or should the entire UDI be excluded and exemption documented?

Christina Savisaar: Are you referring to application identifiers that are not production identifiers?

(Shantel Harper): No.

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Linda Sigg: I think she's talking about the delimiters -- the parenthesis zero one the parenthesis one. Is that what you're talking about?

(Shantel Harper): Yes. Exactly.

Linda Sigg: So you're asking if you can eliminate the delimiters in order to have enough space to put the entire UDI?

(Shantel Harper): Yes. Or are the delimiters required as part of the mark?

Linda Sigg: I think well, they would be required because without them, we wouldn't know which piece of the production identifiers you'd be referring or when the DI ended and the PI began.

(Shantel Harper): Okay. So that goes along with our understanding that they are required.

Linda Sigg: Yes.

(Shantel Harper): So if the space only allows for the DI and the PI without the delimiter, is that acceptable?

((Crosstalk))

Linda Sigg: No. For the human readable, it needs to be the full UDI. And then there's always the option of putting the AIDC as well.

Anita Rayner: Or instead.

Linda Sigg: Or instead of, right.

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(Shantel Harper): Okay. So not to have it without. It's not an exemption.

Christina Savisaar: Correct.

(Shantel Harper): Okay. One other question -- so if there were devices that were directly marked prior to the issuance of this final guidance without the application identifiers or the delimiters, what's the expectation of FDA? Would we have to rework those devices?

Christina Savisaar: They wouldn't be considered to be UDI compliant if they do not have the correct form of the UDI on the device.

(Shantel Harper): Okay. All right. Thank you.

Coordinator: (Nicholas Jacob), your line is open.

(Nicholas Jacob): Hi, thanks. I had another question regarding inventory. For class one products, you said you weren't going to enforce the UDI direct part market requirement until I think it was September 24, 2022. So does that mean every product that's in inventory -- so built on September 23, 2022 and prior -- has three years to meet the requirement? Or to conform to the requirement?

Christine Savisaar: At this point, we issued the letter in June that in regard to class one and unclassified devices, it gives our intent to extend. But to formalize that policy, we are issuing a guidance which is expected in 2018 and the specifics of the policy related to the enforcement discretion will be in that guidance. And I unfortunately can't discuss that at this time.

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(Nicholas Jacob): Okay. So I guess as it is today, I have the same question. So for class one products built on or before September 23, 2020 have three years to comply to the requirement. Is that correct?

Christina Savisaar: No. The requirement for the exception under 801.30(a)(1) for inventory provides a three-year period of time for the label requirement under 801.20. The direct mark requirements under 801.45 if you are past the direct mark compliance they come into play as soon as there's a requirement under 801.20.

So after that three-year time period, both the label and direct mark requirement kick in.

(Nicholas Jacob): Okay. So I'm still not clear. So the class one devices have until September 24, 2020 to comply. But we have three years for inventory to comply for products that are built prior to that date?

Christina Savisaar: Like I said, the particulars for class one will be in an upcoming guidance document.

(Nicholas Jacob): Okay. I was just wondering what timeline we should march to today, you know, with the guidance that's out currently. Hello?

Linda Sigg: As Christina stated, the guidance will be out in 2020 and we will have more information…

Christina Savisaar: 2018.

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Linda Sigg: My gosh, in 2018. Thank you. And there will be more information there. Unfortunately, we didn't talk about grandfathering the letter, so we can't go into the details at this point in time. Apologies.

(Nicholas Jacob): Okay. Thanks.

Coordinator: (Anti Dumatir) your line is open.

(Anti Dumatir): Hey. Thanks for the good presentation. In AIDC reference, RFID technology was mentioned. Just to clarify, so does using RFID technology on a device, does it fully satisfy the UDI direct marking requirement?

Christina Savisaar: Yes.

(Anti Dumatir): And it applies to both class two and class one, I assume.

Christina Savisaar: It could be potentially used for any device class.

(Anti Dumatir): Thank you.

Coordinator: Thank you. (Cathie Camprilla) your line is open.

(Cathie Camprilla): Hi. Thank you. My question is for a device that's been labeled as single use by the manufacturer, but it's been subsequently reprocessed by another manufacturer. Is the reprocesser required to then apply a direct mark?

Christina Savisaar: Is it being reprocessed for just another single use?

(Cathie Camprilla): So it'll always be single use. But it can be reprocessed multiple times.

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Christina Savisaar: There is an exception under 801.45(d) that I highlighted that's built into the regulation that applies to those types of devices. So they are not required to be direct marked when they're being reprocessed for an additional single use.

Anita Rayner: But isn't it also true that if you are a reprocesser of single-use devices, you would be considered, when you're reprocessing that single-use device, you would be considered a labeler and have your own UDI label requirements that would apply to that device?

Christina Savisaar: Yes, that's true.

(Cathie Camprilla): Right. Yes. Okay. Understand that point. But it won't be direct marked. It will just be labeled with the UDI.

Anita Rayner: Right.

(Cathie Camprilla): Okay. Thank you.

Coordinator: (Alan Kent), your line is open.

(Alan Kent): Hi. I just have a question on the, excuse me, the DI number. I have a couple of people that are asking the device label number that I'm putting on and I'm putting one package into one box, that the box needs to be a different DI as a level. Or can I put the same DI number?

Christina Savisaar: I think the requirements for labeling are really outside of the scope of this webinar. But please submit that question to the UDI help desk because we deal with the whole gamut of UDI issues through help desk.

(Alan Kent): Okay. No problem. Thank you.

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Coordinator: (Michelle Montacino) you may ask your question.

(Anderson Geraldo): Hello. How are you. Yes, it's actually (Anderson Geraldo). So my question is regarding some of the dates. So I understand that the UDI the new rules become applicable September 24, 2018. So anything we manufacture before that we have pretty much three years to use it without having to rework it. So anything that we didn't use by September 24, 2021 that has to be reworked. Is that correct?

Christina Savisaar: Are you talking about a class one device?

Linda Sigg: Class two.

(Anderson Geraldo): Class two.

Christina Savisaar: The compliance date for class two labeling was 2016. The compliance date for direct marking is 2018. Anything made before the 2016 compliance date has until 2019 to comply with label and direct mark if the inventory has not been consumed.

(in the background with caller): (Unintelligible) direct marking.

(Anderson Geraldo): Okay. So just to make sure we're clear, if we're talking only about direct marking, it's still 2019?

Christina Savisaar: Yes.

(Anderson Geraldo): Okay. Perfect.

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(in the background with caller): Because the UDI…

(Anderson Geraldo): Well that was all the questions I had. Thank you very much.

Woman: Yes.

Coordinator: Thank you. (Nasreen Kabani) your line is open.

(Nasreen Kabani): Hi. I have a question. Does an (unintelligible) thermometer need a UDI? It's considered a class two. Just wondering if it could still need it (unintelligible) because it's only a thermometer.

Christina Savisaar: It depends on whether or not the device is intended to be used more than once on different patients and intended to be reprocessed -- that is, undergo a high level of disinfection or sterilization between uses on multiple patients.

(Nasreen Kabani): It is going to be used by a baby, you know. Because I'm selling baby products right now. I'm thinking of a thermometer, an (unintelligible) thermometer right now. And it's going to be like a home use. It's not to be used in a hospital or anything. So it's actually going to be used by just one child. And I'm not quite sure if it really needs to be pretty much disinfected or anything like that, like the hospital instruments are.

So, if you can tell me if it would require a UDI and if it does require a UDI, does it - would we need to put the UDI marking on it also or not necessarily?

Christina Savisaar: Well, most devices require a UDI on the label, which is separate from what we're discussing today. It sounds like it's not a device that undergoes high-level disinfection or sterilization and is not used on multiple patients. So it's not likely required to be direct marked with the UDI.

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But if you want a more definitive answer on your specific situation, then we encourage you to submit to the UDI help desk.

(Nasreen Kabani): Okay. I can do that. And one more quick question is that if it does require a UDI, then my manufacturer would have a UDI. Can I use his UDI and make my own products with my own brand? Or do I need to have my own UDI for it?

Christina Savisaar: You mean on the label?

((Crosstalk))

Christina Savisaar: There is a definition of labeler - well, this is outside of the scope of the direct mark guidance. There is a definition of labeler under 801.3 and it pertains to who causes the label to be applied. And you should examine that definition to figure out who is the labeler in your situation. And the labeler is the entity that is responsible for the UDI.

(Nasreen Kabani): Okay. And the statute number that you were mentioning was 801?

Christina Savisaar: 801.3 is where the definition of label can be found.

(Nasreen Kabani): Okay. I'm going to look at that. I really appreciate your helping out. Thank you.

Coordinator: (Shannon St. James) your line is open.

(Shannon St. James): Hi there. I was just wondering if you could provide us with some examples of specific alternatives to UDI requirements like direct marking?

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Christina Savisaar: On our web page, there is a listing of alternatives that we have granted that if we grant them to one labeler, other labelers may take advantage of those alternatives. And I don't believe any of those pertain to direct marking.

Anita Rayner: Yes, I believe that's the case, Christina. But I also want to add and point out that the direct marking regulation itself does include all of those exceptions related to if direct marking might interfere with safety or effectiveness or if it's not technologically feasible. So I think that those exceptions really cover a host of situations that -- and there are a couple of others, of course -- a host of situations that labelers would encounter in terms of trying to comply with direct marking.

And as Christina said in her presentation, if you determine that one of those exceptions applies, there is no need to submit a request to the FDA. But you do need to document it as stipulated in the regulation -- usually in the design history file for non-class one device.

(Shannon St. James): Okay. That's perfect. Thank you.

Coordinator: Thank you. Next we'll go to (Tom O'Keefe). Your line is open.

(Tom O'Keefe): Hi. Thanks for taking my question. My question also relates to the grace period. I know there have been a few questions on that. I understand the additional guidance for class one will be out next year. I also understand that the compliance date where the clock starts clicking on the grace period starts on the labeling compliance date.

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So for a class two product, for example, that would be September 24, 2016. In an essence there's a one-year extra year after the DPM requirements. So it would be the grace period ends September 24, 2019. That's all clear and in the guidance, an example is given of a product that's manufactured May 1st and that grace period ends September 24, 2019 - excuse me, May 1, 2016 is the example. So that all makes sense.

I guess I'll get to my point. The question is in 801.30(a)(1) it refers to the compliance date and the grace period is any product manufactured prior to the compliance date. And the compliance date again for a class two product is September 2016 and the example is prior to that.

But the question is what about products manufactured after the labeling compliance date but before the DPM requirement? So for example, would the example given for May 1st be the same result if that manufacture date was October 1, 2016? Does a grace period also apply to products that are manufactured in that two-year period leading up to the DPM date or not?

Christina Savisaar: I believe once the direct mark compliance date arrives, then they're required to be direct marked because they're already subject to the label requirement under 801.20.

Just to make sure I'm following the details correctly, you could submit a help desk case to clarify that.

(Tom O'Keefe): Yes. I guess maybe I'll state it another way a little clearer. If my device is manufactured September 23, 2016 the grace period would expire three years later, September 24, 2019. That's pretty clear.

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If my device was manufactured September 25, 2016, and again it doesn't have DPM because it's not required yet, would the grace period still go to 2019 or would there not be a grace period for that specific device?

Christina Savisaar: There wouldn't be a grace period because what's provided in the regulation is for the 801.20 requirement and it's already required to comply with 801.20 at the time it's being manufactured. And so the direct marking compliance is conditioned on - it has a requirement under 801.20.

(Tom O'Keefe): But it's not required to be direct marked until 2018.

Christina Savisaar: That's correct.

(Tom O'Keefe): So I guess all the products leading up to September 24, 2018 that go into stock, does that grace period apply to those and extend out to 2019 is the question I guess.

Christina Savisaar: It does not.

((Crosstalk))

Anita Rayner: For the ones produced after the 2016 compliance date but before the direct mark compliance date in 2018, no it does not.

(Tom O'Keefe): Okay. That seems overly burdensome. So a product manufacturer one day prior to September 24, 2016 can take advantage of the grace period to 2019 but one manufacturer two days later cannot. I'm just trying to understand. That logic doesn't seem reasonable.

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Christina Savisaar: Yes. These are the provisions in the regulation and the regulation inventory exception was based on an exception for the label requirement.

(Tom O'Keefe): Okay, thank you.

Coordinator: Thank you. (Catherine Page) your line is open.

(Catherine Page): Hi. Thank you for taking my call. My question for you as far as an end user in a hospital, I understand consigned versus loaned devices. And we do get consigned items here within the hospital. But if we have instrument trays in surgery, does each individual item have to have a UDI marker on it like a hemostat, a scissor, a retractor -- anything we've purchased after the grandfather date?

Christina Savisaar: Unless the labeler of the device has determined that an exception applies or they've been granted an alternative, then it would be, you know, every instrument in the tray that is intended to be used more than once and intended to be processed would be subject to direct marking.

Anita Rayner: But I believe - did you say that you had already bought the instrument?

(Catherine Page): Yes. If we've already purchased the instrument, are we required as a hospital to put that identifier on?

Anita Rayner: No, absolutely not.

(Catherine Page): Okay.

Anita Rayner: No, once the product changes hands and you are the owner, you do not have any UDI labeling or direct mark requirements.

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(Catherine Page): Okay. But in the future though we need to make sure that the companies that we purchase from have that UDI marker on it, correct?

Anita Rayner: Well, we would advise you to start looking for UDIs. But remember that the compliance dates for these things are staggered based on device class. And for devices that you may already have consigned or loaned in your facility before the applicable compliance date for those devices as stated in the guidance document that we're exercising enforcement discretion and do not expect that companies would be required to go in and now direct mark ones that had been consigned or loaned to you. Does that make sense?

(Catherine Page): Yes, it does. And one last question -- as far as product recall with this UDI marking, will that help us identify the products easier?

Anita Rayner: I think that is the intent.

(Catherine Page): Okay. Great. Thank you so much.

Anita Rayner: Thank you.

Coordinator: Our next question is from (Christina Gucci). Your line is open. (Christina) did you still have a question? You may want to check your mute button.

(Christina Gucci): Hello?

Coordinator: Yes.

(Christina Gucci): Can you hear me?

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Coordinator: We can hear you now. Thank you.

(Christina Gucci): Okay, perfect. My apologies. With regards to reprocessed devices, as part of traceability we currently direct mark the part number and lot number on the part. Since UDI contains the part number and lot number, is it acceptable to no longer include direct marking of the part number and lot number, even if there is allowable space on the device?

Christina Savisaar: I would have to look at the conforming amendment for traceability, but I believe UDI is included in those. And the idea is that under 820 there's some flexibility that if you have a device that needs to be traced by lot or batch, then you determine how that's done. And if the UDI has all of the production identifiers that you would need to do that, then I believe it meets the requirements.

(Christina Gucci): Okay. All right. Perfect. That's exactly what I was looking for. Thank you so much.

Christina Savisaar: Yes.

Coordinator: (Gary Tiemsic) your line is open.

(Gary Tiemsic): Great. Thank you again. Appreciate the second round here. So my question is going back to some of the language. And maybe if there's any guidelines or justifications as to what is defined as easily readable plain text. Is there a, you know, font size or a specification around that?

And then I'm sorry. I have a second question which is around just GS1 standard. Since it's an accredited agency, that would there be any expectation that a labeler if it's feasible to create a direct mark to go smaller than the GS1

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standard specification, since it can be direct marked but not following in accordance with the specifications.

So the first one is the easy readable text spec, if there is any, or guidelines as to what that is. And anything related to the just one standards for minimum sizing, if it's expected to deviate outside of the specifications that GS1 is in order to apply a direct mark.

Anita Rayner: You know, some of the specifics of that I think are a little bit outside of what we can cover here in this webinar. I suggest that you send your question to the help desk and we'll try to address it and perhaps give you some references.

(Gary Tiemsic): Okay. Thank you.

Coordinator: We'll move on to (Jay Mackie). Your line is open.

(Jay Mackie): Good. Yes, back to direct marking and reprocessing. We sell over the counter, long-term products as blood glucose meters. So for the long-term care facilities, they do clean and disinfect between patients. But that's not really a sterilization process. It's basically using disinfectant wipes twice, you know, where the first wipe is to clean and the second in the instructions the second wipe really is to disinfect.

So I don't think that's considered a high-level disinfection. Is that correct?

Christina Savisaar: I don't believe that it is.

(Jay Mackie): So then our meters would not require direct marking for the long-term care facilities.

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Christina Savisaar: It would not require direct marking. As we said, you know, that does not prevent you from voluntarily direct marking -- especially if you think it will be of use to your end users.

(Jay Mackie): And I guess the other point to that would be, I mean, it could comply to the exception as far as stated in 801.45 as far as it already does contain a label on the meter with the UDI.

Christina Savisaar: Yes.

(Jay Mackie): And I guess in a follow-up to that, do I need to document this in our design history file as far as the decision for these products not to consider direct marking? Or is it just face value, basically?

Christina Savisaar: It sounds like it's not a device that is intended to be reprocessed per our definition in the final guidance, so you wouldn't have to document an exception.

(Jay Mackie): Okay. So then I wouldn't have to enter into the GUDID that it's exempt.

Christina Savisaar: Correct.

(Jay Mackie): Okay. Thank you very much.

Coordinator: Thank you.

(Jay Mackie): Thanks for your patience.

Christina Savisaar: No problem.

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(Jay Mackie): You're doing better…

Coordinator: I apologize. I had already clicked on his name. (Daphne Allen) your line is open.

(Daphne Allen): Hi. Thank you very much for this webcast. I just want to clarify that when you're speaking about the requirements pertaining to reuse and reprocessing, do both the situations need to be in place -- that is has to be used for multiple patients and subject to high-level disinfection or sterilization -- or is it an either/or…

(Daphne Allen): …that only one of those needs to be in place?

Christina Savisaar: It's both conditions. It's intended to be used more than once and intended to be reprocessed.

(Daphne Allen): Okay, perfect. And so does that mean that if a device is built for one patient but subject to high-level disinfection, it does not need a direct mark?

Christina Savisaar: That's correct.

(Daphne Allen): Okay. And if it's multiple patients but only subject to low-level disinfection, it does not need a direct mark.

Christina Savisaar: That's also correct.

(Daphne Allen): Okay. Thank you very much.

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Coordinator: Ms. (Chasabordee) your line is open.

(Chasabordee): Hi. Can everyone hear me?

Coordinator: Yes, ma'am.

Christina Savisaar: Yes.

(Chasabordee): Okay. So I was in the implant business for a while a couple years ago. And I was just wondering, so I see on slide seven that you say it does not apply to implants. But I know there is a difference between sterilized packaged implants and non-sterile implants where they're in the trays so they won't have like a label associated with them.

And I was wondering would in that case directly marked implants be okay in that case, since the UDI mark will, you know, go with the implants essentially when they're reprocessed?

Christina Savisaar: This is a situation that many labelers of non-sterile implant devices are aware of. We had sent a letter in November 2014 providing extra time for these labelers because they need a strategy to be able to convey the UDI from the label to the point of use because we expect that especially for implants the UDI will be recorded in electronic health records and end users will want this information.

It does not have to be done through direct marking. There are other strategies that people can use. Some labelers may choose to direct mark the UDI on non-sterile implants for this reason.

(Chasabordee): Okay. And…

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((Crosstalk))

Christina Savisaar: But it would be voluntary.

(Chasabordee): It will be voluntary to direct mark implants?

Christina Savisaar: Given that there are other strategies that they could use to convey the UDI, to point of use, yes.

(Chasabordee): Okay. But it is - you want all the manufacturers to have a plan, but it's not necessarily direct marking.

Christina Savisaar: Correct.

(Chasabordee): Okay. And in terms of deadline for those, will it follow the deadline for class two instruments or implants, in this case for direct marking? Or no, it won't?

Christina Savisaar: In the 2014 letter, since the label compliance date for implants was 2015, we told non-sterile implant manufacturers that they could have until 2016, given that they have a slightly more complex problem to address than simply putting the UDI on the label.

(Chasabordee): Okay. But to ensure that the implants themselves have that information captured, does it - would that labeling date apply? Or will it follow closely to the direct marking labels for class two? Or the direct marking dates for class two?

Christina Savisaar: It's part of the label requirement.

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(Chasabordee): Okay. Thank you.

Christina Savisaar: Thanks.

Coordinator: (Sahar Amadkan) your line is open.

(Sahar Amadkan): Hello?

Coordinator: Go ahead with your question, ma'am.

(Sahar Amadkan): Can you hear me?

Coordinator: Yes, we can.

(Sahar Amadkan): Okay. So thank you very much for the presentation. And I have two questions. So could you just give us briefly an overview of the requirements for combination devices like either a device drug combination devices and devices and like part of the devices is just for single use. Like the other part is for multiple use.

Christina Savisaar: I'm not sure if I understood. Implementation of UDI for combination products is outside of the scope of this. If you have a device component of a combination product that is intended to be used more than once and intended to be reprocessed between uses, then there is an expectation that that would be direct marked unless an exception applies.

(Sahar Amadkan): Okay. And okay. So I think that's clear. I'm good. Thank you.

Coordinator: Thank you. (Orjeda Dervishluri) your line is open.

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(Orjeda Dervishluri): Hello?

Coordinator: Go ahead. We can hear you.

(Orjeda Dervishluri): Good afternoon everybody. I actually had a question regarding -- there was actually somebody else asked the same -- regarding private labeling versus manufacturing. And I just want to reinforce what I understood.

So if we are the manufacturer and we private label for a different company, they would be the ones responsible for the direct marking. Did I understand that correct?

Anita Rayner: It can get a little complex and it depends on the details of the situation and your relationship with the distributers and also what is on the label and whose device it is. So if you want us to give you more specific input, it would probably be helpful for you to include that information in a help desk case so we can advise you more correctly.

(Orjeda Dervishluri): Okay. Thank you. That's all I had.

Coordinator: The next question will be from (Fizel Binyad). Your line is open.

(Fizel Binyad): Yes. Good afternoon. I have a quick question regarding basically marking instruments, with the direct marking of instruments of both components -- the human readable and the machine readable. Can they be separated, like the human readable on one side of the instrument and the machine readable on another side of the instrument? That's one question. I actually have three quick questions.

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The second one -- what is an acceptable size for the human readable to go on the instrument itself? I know it needs to be readable. Because the main reason is the limited space on the device itself.

And the third one is really what is the expected lifetime? I mean, we talk - usually people talk about sterilization cycles. Is there a number that can be associated with that as far as what's acceptable?

Christina Savisaar: So I'll take these one at a time and hopefully I will remember them all.

(Fizel Binyad): All right.

Christina Savisaar: Your first question in regard to putting the human readable on one side and the AIDC on another, for purposes of direct marking, that would be acceptable if you're using both forms. They don't necessarily have to be right next to each other.

In regard to your question about the size of human readable, an earlier caller was asking about standards and references for this. And we don't have those readily available. But if you would like to request more input through help desk, we'll see what references we can provide.

And I am forgetting your third question.

(Fizel Binyad): Third one, yes third one is the typically lifetime the mark goes through interpreted as the number of sterilization cycles…

((Crosstalk))

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Christina Savisaar: Yes. That in terms of the expected usage, that is something that it's up to the manufacturer to determine, you know, based on your experience with your devices and information you have to estimate that to the best of your ability.

Linda Sigg: But the direct mark is…

(Fizel Binyad): Thank you.

Linda Sigg: …expected to last the lifetime of the device.

Christina Savisaar: Yes.

(Fizel Binyad): Okay. Thank you.

Coordinator: (Shantell Harper) your line is open.

(Shantell Harper): Hello. One other question -- I had (unintelligible) that will not fit on the device and AIDC cannot be used for some validation reason or material constraint. Would the technologically not feasible exception apply in that instance?

Christina Savisaar: If there is a reason why none of the available methods of marking can be used on a certain material, then that could be a rationale for applying a technologically unfeasible exception.

(Shantell Harper): Okay. Thank you very much.

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Anita Rayner: But again, that would have to be documented by you, properly documented according to the regulation.

(Shantell Harper): Yes, absolutely.

Coordinator: And our last question will be from (Richard Woo). Your line is open.

(Richard Woo): Hi. Per 801.40(d) reusable class one instruments only have to have the UPC on the label and does not need to be direct marked. Is that correct?

Christina Savisaar: That is correct.

Anita Rayner: Except that it doesn't require - class one devices don't require a UPC on the label. It could be either a UDI or a UPC.

(Richard Woo): So it can be a UDI? Okay.

Anita Rayner: Yes.

Linda Sigg: And you can still voluntarily direct mark.

(Richard Woo): Yes, of course. But do we need that exemption checked off in the GUDID?

((Crosstalk))

Christina Savisaar: If you are using a UPC to serve as a UDI…

(Richard Woo): No, I mean to not direct mark if we're using a UPC or UDI…

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Christina Savisaar: If you're…

(Richard Woo): …in lieu of direct marking.

Christina Savisaar: That pertains to the exceptions under 801.45(d). If you are determining that you're going to use a UPC instead of a UDI, then technically that UPC serves as a UDI for all requirements - that UPC on the label meets the UDI requirements. And there's not a requirement to direct mark.

If you have a class one device with a UDI on the label, then you would need to direct mark it unless it meets one of the exceptions under 801.45.

(Richard Woo): Wait. So a class one reusable having a UPC still needs to be direct marked unless it had…

Christina Savisaar: No. The UPC meets all - serves as a UDI and meets all the requirements.

(Richard Woo): Okay. And you said a UPC or a UDI label form like a barcode format, correct? Like a UPC is a certain format but a UDI has two extra digits.

((Crosstalk))

Christina Savisaar: Yes. A UDI is a different format than a UPC and there's no requirement that you have to, as (Anita) was explaining, that you have to use a UPC for a class one device. You can use a UDI, but you're not automatically excepted from direct marking if you have a class one device with a UDI on the label.

(Richard Woo): Okay.

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Christina Savisaar: There is a provision where the production identifiers don't need to be included in the direct mark for a class one device.

Anita Rayner: And that's true for the UDI on the label as well. I mean, for class one devices that are subject to UDI, they do not need production identifiers either in the label form or on the direct marking. Only the DI form. I know that goes a little far field and outside your question, but I hope it helps.

(Richard Woo): No, I mean that's part of the question. I'm just trying to make clarify…

Anita Rayner: Class one is a little odd, so.

(Richard Woo): Right, yes. It has that statement in there saying you can use a UPC but you're saying you can use either a UPC or UDI and not direct mark.

Christina Savisaar: Well, the condition under which you would be using the UDI and not direct marking is if one of the exceptions applies. So if you…

(Richard Woo): Okay.

Christina Savisaar: …are using a UDI on the label of your class one device…

(Richard Woo): Then we may have to direct mark.

Christina Savisaar: You may have to direct mark. But you might…

((Crosstalk))

Christina Savisaar: …be using a UDI on the label and an exception might apply and then you would not have to direct mark.

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(Richard Woo): But if we use a UPC, then we do not have to direct mark.

Anita Rayner: That's right. There's no requirement that you do that although again, if the conditions as outlined in the - especially if conditions outlined in the guidance would apply, we would encourage companies to voluntarily direct mark. But there's no direct marking required.

(Richard Woo): Okay. All right. Thank you.

Coordinator: And now I'd like to turn the call back over to Irene Aihie. Thank you, ma'am.

Irene Aihie: Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questions. Today's presentation and transcript will be made available on the CDRH Learn webpage at www.fda.gov/training/cdrhlearn by Friday, December 8th.

If you have additional questions about today's presentation, please use the contact information provided in the slide presentation.

As always, we appreciate your feedback. Following the conclusion of today's webinar, please complete a short, 13-question survey about your FDA CDRH webinar experience. The survey can be found at www.fda.gov/cdrhwebinar immediately following the conclusion of today's live webinar.

Again, thank you for participating. This concludes today's webinar.

Coordinator: Thank you for your participation. The call is now ended, and you may disconnect your lines.

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