Coordinator: Welcome and thank you for standing by. At this time all participants are in a listen only mode. During the question and answer session you may press star 1 on your touchtone phone if you would like to ask a question. Additionally, today's conference is being recorded. If you have any objections you may disconnect at this time. I would now like to turn our meeting over to Miss Irene Aihie. Miss Aihie, you may begin.

Irene Aihie: Thank you. Hello and welcome to today's FDA webinar. I am Irene Aihie of CDRH's Office of Communications and Education. Today's webinar is focused on aspects of the unique device identification program. To start we will provide a basic overview of UDI requirements, followed by specific recommendations on getting ready for the global unique device identification database -- also called GUDID.

The goal of these webinars is to help labelers of class II implantable/life supporting/life sustaining, and new class III devices prepare to comply with requirements outlined in the UDI final rule.
Today we have two center experts on UDI with us. First from the Office of Surveillance and Biometrics. Loretta Chi -- Regulatory Policy Analyst -- will present the unique identification program -- UDI 101. After Loretta's presentation we will have a 30 minute break before Indira Konduri -- CDRH's GUDID Program Manager presents Getting Ready for GUDID.

After each presentation we will host a Q&A session during which our presenters will be joined by Anita Rayner -- Associate Director for Policy and Communications -- also with the CDRH Office of Surveillance and Biometrics. Now I give you Loretta.

Loretta Chi: Thank you, Irene, for that introduction. And welcome everyone to this webinar entitled UDI 101. The purpose of this webinar is to give you a brief overview -- a very high level overview of the UDI program --, and to familiarize you with some of the requirements of the UDI program.

We will begin with a background about the UDI program, move on to a discussion of the compliance dates, then we'll talk about general exceptions. At this point the presentation will turn to the UDI requirements themselves. We will talk about the UDI labeling requirements -- including an explanation of what exactly is a UDI. We'll talk about data submission requirements.

The presentation will end with a brief overview of the global unique device identification database -- otherwise known as GUDID. This will segue us to the next webinar entitled Getting Ready for GUDID.

Let's start with a bit of background. The UDI system was authorized under FDAAA in 2007, and FDASIA which was signed into law in 2012 required FDA to modify the compliance timeframe for certain devices. FDA did so when it issued its final rule on September 24, 2013. And you'll see at the
bottom of the slide that there's a link to the UDI final rule if you want to access it.

The UDI system’s objectives are to establish a system to identify medical devices through distribution and use. By use, we interpret this as meaning to point of use or point of care -- usually being used by or on a patient.

The goal of this program is to facilitate rapid and accurate identification of a device, and to prevent incorrect identification. It is intended to enable access to important information concerning the device, thereby reducing medical errors.

It's intended to allow more accurate post-market adverse event reporting so that problems can be identified and corrected more quickly. It is also intended to standardize device use documentation and electronic health records leading to a more robust post-market surveillance system. And it is intended to help manufacturers and others more effectively manage medical device recalls.

So what is a UDI? A UDI is a unique code on a device label, package, or in some instances on the device itself. It is both in human readable -- meaning plain text -- and machine readable format. Here on the slide you see some examples of the machine readable format -- including the 1D and 2D barcoding, and an abstract of the RFID technology.

In fact, if you have a smart phone that has a scanner mechanism, you can actually scan these barcodes and it does come up and say, UDI 101, and today's date.
All of these machine readable formats are acceptable under the UDI rules but for purposes of this presentation we are going to use the 1D barcode as an illustration.

Although the unique identification system is new for devices, the concept of unique identification itself is not new. Most people are familiar with retail store scanning. There are also VIN numbers for cars, and most people in the United States have social security numbers.

In 2004 FDA published a final regulation requiring barcodes on the labels of most human drug products and biological products. Now this requirement is being applied to medical devices.

In order for the UDI program to be successful four steps need to be completed. First FDA needs to build a regulatory and technical framework for the UDI system -- which it did when it published the final rules on September 24, 2013.

Next, the medical device industry needs to comply. UDIs need to be placed on device labels and packaging, and in some instances on the devices themselves. And the required data needs to be submitted to GUDID. Last, but by no means least, all stakeholders need to work together to facilitate the adoption and implementation of the UDI system across the supply chain, and ultimately get it adopted by the healthcare community.

The UDI rule applies to every medical device as that term is defined under the Food, Drug and Cosmetic Act. And it applies to all medical devices that are in commercial distribution on the applicable compliance dates.
Although most of the provisions of the UDI final rule went into effect in December 2013, the UDI program is a transformative and important program for the medical device industry. To give everyone enough time to prepare and to ensure orderly compliance with the regulations, FDA has set compliance dates for the UDI requirements to be phased in over a seven year period.

These compliance dates are based primarily on device classification with the compliance dates for higher risk devices occurring first. So you see on the slide a group of key compliance dates. You'll see that the first compliance date, September 24, 2014 covered class three devices, as well as devices licensed under the Public Health Service Act. The next compliance date is September 24, 2015, and applies to implantable, life supporting, and life sustaining devices. Class two devices have a compliance date of September 24, 2016.

Keep in mind that devices that are required to be directly marked -- these are devices that are intended to be reused and reprocessed between uses -- have to keep in mind that there are two compliance dates that apply to them. They may be the same date, or they may be a separate date. They may be a different date. So you see that direct marking requirement for implantable, life sustaining, life supporting devices is also September 24, 2015. These are the key compliance dates. If you want more details on compliance dates you can access the link that's on the bottom of the slide.

There are general exceptions and alternatives to the UDI requirements that are listed under 21CFR801.30. In addition, FDA may grant an individual exception or alternative either on its own initiative or in response to a request by a labeler. FDA will be posting these decisions on the UDI website.
There are general exceptions that are set out in 21CFR801.30 -- and I've listed some of the key general exceptions. These include the class one devices that are CGMP exempted, individual single use devices sold and stored -- they're sold packaged together, sold together in a package, and intended to be stored together in that package until removed for use. These individual single use devices are not required to have UDIs, however the package itself will be required to have a UDI.

UDI requirements to not apply to the devices that are still under investigation, or devices used solely for non-clinical use -- such as research and teaching. Also devices intended solely for export from the U.S. are not required to have a UDI.

Individual devices in convenience kits are exempted from UDI requirements, however the convenience kit itself is considered a device, and therefore the convenience kit will be required to have a UDI. There is a three year grandfather exception for devices that are packaged and labeled for sale prior to its applicable compliance date. These devices have three years before they are required to have a UDI.

As I said, these are key general exceptions. There are more, and you can see the full list of exceptions under 21CFR801.30, and the link is on the bottom of the slide.

So let's now sort of summarize the basic UDI requirements. First, a UDI is required on every device label and device package, and in some cases on the device itself unless an exception or alternative has been granted by the FDA.

Second, key information -- both on the label and the UDI -- is required to be submitted to the GUDID. Finally, dates on the device label -- certain dates on
those device labels must be in a specified format by the device's UDI compliance date.

The FD&C Act defines label as a display of written, printed, or graphic matter upon the immediate container of any article. And therefore, the UDI needs to be placed on the label.

If your package is a retail package and the UDI is on the immediate container of the article - of the device, and then there is a clear plastic wrap around that container through which you can clearly see the UDI, there's no requirement that the UDI be on that plastic wrap.

The labeler is the entity responsible for complying with UDI requirements. The term labeler is created under the UDI rules and is defined as any person who causes a label to be either applied to a device, or replaced or modified. And in both cases, the intent is that the device will be place in commercial distribution, and the label will not be subsequently modified or replaced.

Generally it is the device manufacturer that is the labeler. But that is not always the case. The term also includes device re-packagers, device re-labelers, re-processers, and assemblers of convenience kits. Distributors who only place their name and contact information on the label without changing the label any further are not considered labelers.

Another role that is important to understand is that of the accredited issue agency -- or IA. Every labeler is required to work with one or more IAs to develop a UDI. FDA accredits issuing agencies. FDA accreditation requires issuing agencies to conform to certain international standards. The FDA may revoke an IA's accreditation if the IA fails to conform to these standards, or engages in other types of wrong doing.
FDA has accredited several issuing agencies, and labelers are required to work with at least one. However, FDA does not recommend one issuing agency over another. And in the next to last slide in this presentation you will see a link to the FDA accredited issuing agencies.

So let's go back to what is a UDI. It is a mark on a device, device label, or device package. If it is on the device label or package, the UDI is required to be both in plain text form -- meaning human readable form -- and machine readable form. If the UDI is required on the device itself -- as in the instance of devices that are intended to be reused and reprocessed between uses -- the UDI can either be in plain text or machine readable form. Both are not required.

Now let's turn to the make-up of the UDI itself. UDI is a unique alphanumeric code. It is the sum of both the device identifier -- or DI -- and the production identifier -- or PI. Here we have a fictional example of a device label with the UDI shown as a single barcode.

Now keep in mind that this is a fictional label. This is something that we developed ourselves. This is a fictional barcode, and it is just an example of what a barcode or a machine readable UDI can look like. Don't think that every UDI has to look like this. And in fact, it's shown as a single barcode. It doesn't even have to be a single barcode. And as I said earlier in the presentation, there are other forms of machine readable formats that are acceptable such as RFID technology.

The numbers below this barcode are the human readable form of the UDI, and the barcode is the machine readable form. Both are required on the device unless the - on the device label and package unless the labeler receives an
exception or alternative. So again, the UDI comprises the device identifier -- the DI -- and the production identifier -- the PI.

Now let's parse the different parts of a UDI. The DI is a mandatory fixed portion of the UDI that identifies both the labeler and the specific version or model of a device. Once assigned to a specific model or version of a device the UDI never changes. If a different version or model becomes available, then a new UDI will be required for that new version or model.

The DI serves as the primary key used to look up information about the device in GUDID. Only one labeler can be associated with each DI. The production identifier is the variable portion of the UDI. When certain information is on the label, it should be on the UDI as well. This information includes lot, batch, or serial number, expiration date, or date of manufacture.

Note that class one devices are not required to include PIs in their UDI. To bring date formats in line with international standards, dates on the label that are intended to be brought to the attention of the user -- such as manufacturing date and expiration date -- must be in the following format: four digits for the year - two digits for the month - two digits for the day. Therefore in this example, January 30, 2014 will be written as 2014-01-30. The compliance date for the date format requirements is the same compliance date as for the label and date of submission requirements.

Now let's talk about packaging. UDI regulations define device package as a package that contains a fixed quantity of a particular version or model of a device. Each level of packaging requires a new UDI. Here are examples of levels of packaging. The base package is the lowest level of a device package containing a full UDI.
This example is a catheter that is wrapped, and UDI is on the wrapping. In this example the base package primary DI is 1001. Keep in mind that when the labeler assigns DIs to its devices it is according to the standards set by the issuing agency. This primary DI that we're using is fictional. It's an example. Your DIs will not be 1001.

The next level of packaging -- say these catheters, these individually wrapped catheters -- are then placed in a box of 30. That box of 30 is the next level of packaging and will require its own unique DI. In this example it is 2001 -- again, a fictional DI. Now let's say these same catheters are also boxed in boxes of 50. The boxes of 50 is a different next level of packaging -- second level of packaging -- and it will require its own unique DI -- which in this example is 2002.

Now let's go back to the box of 30. Say 12 boxes of 30 are placed in a case. This case will be the third level of packaging and will require it’s own DI -- which in this hypothetical example is 3001.

There is often confusion about what constitutes packaging and what requires a UDI. Here are examples of what we do not consider packaging, and do not require a UDI. Any type of wrapping intended to protect the device from damage during shipping is not considered packaging. So therefore bubble wrap, Styrofoam containers, paper wrapping -- these are not considered packaging requiring a UDI.

Pallets -- especially when the number of units differs from pallet to pallet -- are not considered packaging. Shipping containers used to transport devices -- particularly when the contents differ from one shipment to another -- are not considered packaging. So for an example, when Amazon fulfills a customer order by putting in different products to fulfill the order, the boxes that these
products are placed in for shipment is not considered packaging, and do not require a UDI.

Let's go back now and review the UDI system which has two parts. There's a labeling requirement -- which I've already discussed -- and there's a data submission requirement.

Key information from the UDI is required to be submitted to the global unique device identification database -- otherwise known as GUDID. The GUDID serves as a repository of key device identification information. The GUDID only contains the DI -- which serves as the primary key to obtain device information in the database.

PIs are not submitted to, or stored in GUDID. The GUDID does contain however, production identifier flags to indicate which PIs you can expect to see in the UDI. Keep in mind that GUDID does not contain any patient identification information or PII.

Here's an overview of the GUDID system. There are two methods by which you can submit your data. You can either use the GUDID web interface or the HL7SPL. The web interface allows for only single entry submission while the HL7SPL allows for multiple entry submissions simultaneously.

Here's an example of a web interface that is displayed in the GUDID. The GUDID holds all required data elements. The list of required data elements can be found in the UDI - sorry GUDID resources page. The link to this resources page is at the second to last slide of this presentation.
Now keep in mind that this example of a DI record is only one page. It's actually multiple pages, so I don't want you to think that this entry is only one page.

Labelers who need to submit DI records into GUDID must first get an account. So instinctively you might think that the first step will be to go get a GUDID account. However, it would be better to first prepare yourself before you apply.

We have developed an elaborate checklist detailing what you should do to get prepared. This includes reading our guidances, organizing your information, and establishing SOPs for records management and GUDID submissions. There are links on this slide to take you to these various resources, and this will of course be discussed in more depth in the webinar titled Getting Ready for GUDID.

As I said at the beginning of this presentation, this is primarily intended to provide a very high level overview of the GUDID program and some of the requirements. If you need additional information I've listed here additional resources which may -- and links -- which may give you more information.

Keep in mind that we are here, and able, and willing, and able, and ready to help you both in establishing your account, and to answer any questions that you might have. And I have here on this slide a link to the UDI help desk where you can submit your questions. Thank you for joining in on this webinar.

Irene Aihie: We'll now take questions.
Coordinator: Thank you. At this time we will begin the question and answer session. To ask a question from the phone lines please press star 1. You will need to unmute your line and record your first and last name clearly when prompted. To withdraw your question please star 2. Once again, if you would like to ask a question from the phone lines please star 1. You will need to unmute your line and record your first and last name clearly. One moment for our first question please.

Our first question is coming from (Tom Mullen). (Mr. Mullen), your question is up at this time.

(Tom Mullen): Hi Loretta. Thank you for the overview. Going to slides 21, 22, the question is - relates to shipping to a distributor as opposed to an end user. Is there any distinction that's made in the UDI requirements for the labeling of the case cartons to a distributor as opposed to shipping directly to a customer?

And in this particular instance, product could be shipped to a distributor in varying quantities of 12 to 24 per case. And then that distributor then sends out on a one each basis to the end user. Thank you.

Loretta Chi: The definition of packaging for requiring a UDI on the package is that the package is a fixed quantity. If you are shipping to a distributor and the quantity is not fixed, then that is not considered packaging. It is considered a shipping container.

(Tom Mullen): Okay. Thank you.

Coordinator: Our next question comes from (Lee Weinstein). Your question is up at this time.
(Lee Weinstein): Hi. Yes, thank you. My question regards to the reuse. I manufacture a biofeedback device which is wearable, and it's used to measure muscle activity on someone's head to indicate whether they're clenching or grinding their teeth. It's designed to be used in sleep. So a dentist might buy one of these and loan it out to a patient to measure how much they clench and grind in their sleep.

The device is quite small, so I'm thinking this is reused because it's used on different patients. And does that mean that they - this entire label is going to have to be placed in the device itself?

Loretta Chi: When you say label, the requirement is that the UDI be on the device, not necessarily the entire label. And in fact, the UDI can be both - can be either the human readable format or the machine readable format. Both are not required.

(Lee Weinstein): Okay. So the UDI part of the label, just the device identifier itself will need to be on a -- in this case -- a label that's attached to this device which is about the size of a wristwatch?

Loretta Chi: Yes. We're not going to - we're not specifying the manner in which the UDI will be placed permanently on the device.

(Lee Weinstein): Right. Right. But the way I place identifiers right now is with a label.

Loretta Chi: That's your decision. Yes. (unintelligible).

(Lee Weinstein): And - okay, so I'm interpreting this correctly to say that my device is considered a reusable device since it would get used - could be used on more than one patient. And so the UDI would have to be on the device itself?
Loretta Chi: We are in the process of drafting a guidance that talks about the direct marking requirements and reprocessing. And unfortunately because the guidance is in development, we're not able to discuss it in more detail at this time.

(Lee Weinstein): Okay. Thank you very much.

Anita Rayner: This is Anita Rayner. Can I just add a comment to what Loretta said? I think it's probably obvious to everyone, but just to reiterate that the direct marketing requirement -- the permanent marking on the device itself -- is an add-on to the UDI labeling requirement -- the label being defined in the act. And I'm going to paraphrase basically as the printed material being on the immediate - on the label of the immediate container of the device, and the direct marking being some sort form of permanent marking on the device as Loretta said.

Loretta Chi: I think the reason why Anita is discussing this is because there appears to be some confusion about what the direct marking requirements are. It is the UDI that needs to be directly marked, and has to be either human readable or the machine readable format.

There's no requirement - under the UDI rules there's no requirement that the entire label be permanently marked onto the device. And as I said earlier - and also to reiterate what I said earlier in one of my slides, there are two compliance dates that people have to be aware of if their device needs to be directly marked. There is the label and data submission compliance date, and then there's the direct mark compliance date.

(Lee Weinstein): I understand, and my device is not implantable, so the compliance date is not this year, but I do want to understand what I need to prepare to do. So from
what you just said, the number needs to be on there -- on the device itself because it's reusable -- does that mean that the number - the UDI number needs to be on the device itself in both human readable and machine readable format, or is it sufficient for it to be on the outer label in both of those forms and on the device itself in only one of those forms?

Loretta Chi: If it is on the device itself it's acceptable to be in one of the two forms, and on the device label and packaging it is required to be in both forms.

(Lee Weinstein): Thank you very much.

Coordinator: Our next question comes from (Janie Batita). Your question is up at this time.

(Janie Batita): Hello. I have a question. We currently mark our primary packaging labels with GTIN global trade identification numbers. Would that type of identifier satisfy the UDI requirement?

Loretta Chi: Yes.

(Janie Batita): Okay, so our next step since we've established our UDIs was to go to the GUDID registration process?

Loretta Chi: Yes.

(Janie Batita): Thank you very much.

Coordinator: Our next question comes from (Amelia Daily). Your question is up at this time.
(Amelia Daily): Hello. Thank you for the nice presentation. I am calling from a manufacturer who makes a HIV device. It is single use only. The device itself and its components are instructed to be disposed of after single use. Does that mean - in reading the general exceptions that we are required to place a UDI on this device?

Loretta Chi: I am - I can't under - Based on your description I cannot quite answer the question because I don't have a full picture of what your device is. So I think it would be better if you were to put in a more descriptive detail of your device, and so for maybe even a diagram of it to help desk.

(Amelia Daily): Okay, yes. I will do that. Now, say for instance -- let's just be hypothetical here -- that they do decide it is individual single use. If we put those in packages of 50, would that larger version require a UDI?

Loretta Chi: I'm a little confused. So you say that the - I'm sorry.

(Amelia Daily): Go ahead.

Loretta Chi: You say that it's a single use device and it's packaged together.

(Amelia Daily): Say for instance you wanted to ship 50 single use devices.

Loretta Chi: Are these devices intended to be kept in the same package until removed for use?

(Amelia Daily): They are kept in individual packages.

Loretta Chi: Look, I'm still not - I'm sorry, I'm still not completely gathering this. When you say they're kept in individual packages, you mean they're taken out - all
right. So you have individual use devices that are in their own - each in their own package, and then the packages are put together into another box?

(Amelia Daily): Correct.

Loretta Chi: Then that's a next level of packaging that will require its own DI.

(Amelia Daily): Okay, so even if it is qualified as this individual single use device, and therefore exempt from UDI...

Loretta Chi: Well, the single use exemption only applies if it is a device that is placed in the package, shipped in that same package, and intended to be kept in that package until use.

(Amelia Daily): Okay, so combining them and putting them in a larger carton would immediately remove that exemption?

Loretta Chi: Well, it's because they're not intended to be kept together in that package until use. That's what takes it out of that exemption - exception. I'm sorry.

Anita Rayner: To add to what Loretta was saying, I think the idea with the individual single use device exception is that if you've got a number of single use devices all packaged together that stay in that larger packaging and are perhaps removed one by one from that larger - from that higher quantity set of packaging, the one UDI that needs to be applied is on that higher level of packaging because it is available at the point where that - perhaps one or more than one of those individual devices is used.

(Amelia Daily): I understand. Okay, thank you for that clarification.
Coordinator: Our next question comes from (Charity Hobel). Your question is up at this time.

(Charity Hobel): Hello. I need a clarification on the direct marking for implantables. On slide nine you had the direct marking date of December 24, 2015 for implantable, life sustaining, and life supporting devices, and in the federal register there was an exemption for implantables.

Loretta Chi: Let me take a look at the slide for a minute. No, yes. Right. There is no direct marking requirements for implantables.

(Charity Hobel): Okay, so just life sustaining and life supporting?

Loretta Chi: I apologize for that slide. I'll change it before it goes up on the web.

(Charity Hobel): Thank you.

Coordinator: Thank you. Our next question comes from (Maggie Pople). (Miss Pople), your question is up at this time.

(Maggie Pople): Yes, thank you. We manufacture a class two medical device that is software only for a PC, and iPhone apps. Where would we put the UDI on that? Would it just go on one of the - like the front page of the tool, the website and the app, or?

Loretta Chi: I didn't get into standalone software -- and software which is part of a component of a device. However, standalone software that is distributed in packaged form must have the UDI both on the package, and also when you start the software you have a start screen. The UDI should come up on that
start screen. If you have some kind of downloadable software, then the UDI needs to come up on the start screen.

(Maggie Pople): Okay, so for the app it would be on the start screen where there's a login, and on the website would just be on the login screen? Would that be good? Because there's no downloadable, and there's no packaging. It's just a website that the physician has to prescribe that the patient can go to and utilize.

Loretta Chi: We haven't really come across this question before about websites. So could you do me a favor and submit this to help desk and we'll...

(Maggie Pople): Great, thank you so much.

Coordinator: And our next question comes from (Lauren Sally). (Miss Sally), your question is up at this time.

Man: Hello. I have a question about breaking out the UDI barcode. You did mention that it does not have to be a single barcode. And so my question is in two parts, that just to verify the DI and the PI can be two completely separate barcodes.

And the second question is we are considering putting the DI on the bottom of our product. I there any - are there any limitations where on the packaging that the barcodes appear?

Loretta Chi: To answer your first question, yes, you can divide the DI and the PI into separate barcodes. I actually - he should talk to the IA, right? You really need to confer with your IA to see if your format conforms to their standards.
With regard to where you place the UDI, I don't recall there being anything in the regs that specifies where it needs to be placed. It just needs to be placed on the label and on the device packaging.

**Man:** Okay.

**Loretta Chi:** But having said that, the purpose of the UDI is to make it visible. So I'm not sure the bottom is the best place to place a UDI.

**Man:** This is a - yes, this is a small kit. Say, you know, 8 x 10 x 5 kit that would, you know, go on - be sitting on a lab bench or in a cabinet.

**Loretta Chi:** Yes, I mean, again, we don't specify where the UDI has to be placed.

**Man:** Okay.

**Coordinator:** Thank you. Our next question comes from (Gustavo Barbela). Your question is up at this time.

(Gustavo Barbela): Hello. I have a question obtaining - the purpose of obtaining the barcode. I tried to do it from - through internet, but I'm not a resident from the United States. Actually I'm overseas. So when I tried to do the process, the only address that is allowed me was to - was a U.S. address -- which I don't have for now. So I wonder how can I obtain that, or if I can put my company address that is in the U.S.

**Loretta Chi:** Are you importing the products into the United States?

(Gustavo Barbela): No, no. The product is U.S. manufactured. It's FDA approved, and the fact in case on my name. But I moved. I moved to another country. And the
product is still manufactured - being manufactured there. So I am in charge of doing all this process. But my address - my permanent address is not in the U.S.

Loretta Chi: Okay, where is the product being manufactured?

(Gustavo Barbela): New York.

Loretta Chi: New York.

(Gustavo Barbela): Yes.

Loretta Chi: And your - then that means that the manufacturing facility that is being - that you're using to manufacture products should be registered and listed.

(Gustavo Barbela): Yes. Well, we have the company...

Loretta Chi: Therefore, it is that manufacturer that is the labeler. And therefore it is their address that needs to be placed...

(Gustavo Barbela): But it's me. I am the president of the company.

Loretta Chi: I understand that it is your product, and that you are the 510K holder. However, you are contracting out the manufacture of your products, and therefore it is that contract manufacturer who becomes the labeler.

(Gustavo Barbela): I'm sorry. I'm sorry to interrupt you. We do software, and we are doing the software using many internet tools and everything. So I am the manufacturer. I am running the factory, I am the president of the company that builds the
product, I'm also the 510K owner, so it's me -- the one that has to do this. Can I use my address of my company in the U.S. instead of my home address?

Loretta Chi: You know, I'm getting a little confused. Maybe you'd better submit this to help desk, and we'll parse this out more carefully.

(Gustavo Barbela): Thank you. Thank you very much.

Coordinator: Our next - yes, our next question comes from (Janice Stevens). (Miss Stevens), your question is up at this time.

(Janice Stevens): I've worked for a software vendor who - we do not provide software like out of the box. It is an installation process if you will. And so my first question is for the software UDI requirement, would it be appropriate or sufficient in the help and about screens for our product to have the UDI be the current version of our software? And also would we have any requirements working with issuing agencies for determining that the appropriate UDI?

And then also, like, what would our GUDID registration requirement for being a software vendor. Like I said, the software is not out of the box, off the shelf.

Loretta Chi: How is it - I mean how is it placed in the device? And what's its function in the system?

(Janice Stevens): We have a blood administration model that pretty much replaces the blood admin lab book if you will. So it's a tracking tool as one example. And so it's just...

Loretta Chi: So is this software that's sort of downloadable off the web? Is that...
(Janice Stevens): No, it is not downloadable off the web. It is not off the shelf. It is something that we have to install at our provider facilities.

Loretta Chi: Okay, so it's part of the device itself really. It's a component of the device?

(Janice Stevens): Correct. And so I was just trying to get clarification on - we have several products that are part of our EHR that are several modules if you will that are cleared medical class one and class two devices. We have to...

Loretta Chi: So let me just ask you a different question.

(Janice Stevens): Sure.

Loretta Chi: Is the software separately approved or cleared?

(Janice Stevens): Yes.

Loretta Chi: Okay, I hate to do this to you, but maybe you'd better send that to help desk and we'll consider it.

(Janice Stevens): Okay. Okay, thank you.

Coordinator: Our next question comes from (Deborah Prebe). Your question is up at this time. (Deborah Prebe) or (Pribe).

Man: Yes, hi. I have a question... I'm not (Deb). We have a device. It's a single use device that's packaged in a case of 30. And that packaging is generally a corrugate.
When it gets to its end hospital it's generally a sterile processing department. And in certain instances based on hospital protocol, corrugate isn't allowed into their facility. Therefore we suspect that those devices are then, you know, stored outside of that final packaging. But that's not how we ship them. If that's the case, do those single use devices each have to have a UDI on them?

Loretta Chi: Are those devices wrapped individually?

Man: The device is packaged. It's a box. It's a biological test pack. It's a box. And that's - the box - the device itself is not corrugated. It's a boxed device that could end up in a sterilizer. So the box that the device is printed on -- the information on the box that ends up in the sterile processing unit -- would that box also have to have a UDI on there?

Loretta Chi: And then when it goes to - it goes to central servicing they take it out of the box, and the box gets thrown out?

Man: That's correct.

Loretta Chi: But it's not being reused.

Man: It's not. No. It's discarded after that.

Loretta Chi: And then where does it go?

Man: Sometimes the... Once it goes to central servicing, then it goes to the patient. No, it's usually kept on patient records for evidence that their equipment was sterile. So it's a...
Loretta Chi: No, no, I'm sorry. I'm sorry. Once the device goes to central servicing and is sterilized, then where does it go?

Man: So the device itself doesn't require sterilization. The device itself is a sterility assurance product that says that the conditions in the sterilizer have been met.

Loretta Chi: So the user - the end user is the central server?

Man: Correct.

Loretta Chi: Well then, yes. You put the UDI on the box.

Man: On the case box or on each product box.

Loretta Chi: On each product box, and then you get - then if you have - and then if you box multiple boxes together because of a next level packaging.

Man: Okay. So we would then - so we put them in packages of - if we put 30 devices into a package -- a corrugate package -- and that corrugate doesn't go to the central processing unit, then each of those 30 unique devices have to have a UDI on there.

Loretta Chi: Correct. I mean it can - yes.

Man: Okay. Unless. Now if we didn't use a corrugate box, and then that container could go to a sterile processing unit, then the UDI would only be required on that...

Loretta Chi: No, I don't think that makes any different. Because you say that once it goes to central processing they take it out of the box.
Man: Yes, they do.

Loretta Chi: Yes. So, yes. It would have to be on each individual unit.

Man: Okay, thank you very much.

Coordinator: Our next question comes from (Steven Gorski). (Mr. Gorski), your question is up at this time.

(Steven Gorski): Hello. I have a two part question. First of all, for a disposable, single patient use flow sensor that is an accessory to ventilators -- so I believe that accessory would be applicable this coming September -- what would be the labeling requirements on the disposable sensor itself?

And then given that it's in bags of 10 and in individual bags as well, what would be the expected class through these resources -- the UDI issuing agencies -- the class universe. Is it $100, is it $1000, or is it $10,000? Thank you.

Loretta Chi: I'm afraid you're going to have to go talk to the individual IAs about their costs and fee structure because we don't get involved in that.

(Steven Gorski): There's no concept at all of what the costs or fees might be? Not even a hint?

Loretta Chi: You can just contact - just contact one of the IAs and they'll give you that structure.
(Steven Gorski): Thank you. I'll do that. As far as the disposable flow sensor for a ventilator which is - ventilators are coming online, what would be the expectations on the bag versus the individual device given that they're single patient use?

Loretta Chi: If they're single use device then there is no requirement to have the direct mark on the device itself. However, the wrapping - the wrapping of the device will be required to have a UDI.

(Steven Gorski): Okay. Do you know of any, like, web forums that are starting, like, on wraps or anything as far as people discussing these things amongst ourselves? I can check that, but if you have any pointers, that would be helpful. That's all I have, thanks.

Loretta Chi: Was that a question?

(Steven Gorski): The question was do you know of any web forums that have started around UDI that you can recommend, or only the FDA's guidance information?

Loretta Chi: No, no, there's forums on LinkedIn and so forth.

(Steven Gorski): Okay. Fair enough. Thanks.

Loretta Chi: But we don't endorse the LinkedIn sites. There's just - it's just an informal conversation between people outside of FDA.

(Steven Gorski): Great. Thanks so much.

Coordinator: Our next question comes from (Victor Hernandez). (Mr. Hernandez), your question is up at this time.
(Victor Hernandez): Thank you. I have a question. Our hardware uses software, and the hardware sometimes is configured differently. Would each configuration need a UDI -- unique number?

Loretta Chi: Okay, I didn't really get into how you determine what is a version or model of a device. It is up to the labeler to determine whether a change to a device constitutes a new version or model. So if the labeler itself decides that a change to the device does bring it up to a new version or model, then you'll need a new DI. However, if you don't consider it to be a new version or model, then you are not required to have a new DI.

(Victor Hernandez): Okay. And I have another question. Thank you. We sell audiometric equipment, and so we have accessories like earphones. Would those also require a UDI as well?

Loretta Chi: If these accessories are sold separately, then yes, they are required to have a UDI.


Coordinator: Our next question comes from (Navine Irian). Your question is up at this time.

(Navine Irian): Okay. Hi. So I have a couple of questions. One is the distributor of class one and two devices, they do add their own parts number on the product, but they don't obstruct the original manufacturer's information. Would they - so they do it for inventory purposes and the sell it under an inventory part number. Would they need to have their own UDI?

Loretta Chi: I would say that if the only change is that they're placing on the label is their contact information, their name, and then some kind of internal inventory
number or something that is obviously not - you can't confuse it with the UDI, then I would say that they're not required to have - they're not a labeler.

(Navine Irian): Even though they sell it by that (unintelligible) number and take complaints against that new part number?

Loretta Chi: I'm thinking through some of the distributors I've dealt with, and I think part of the challenge in this is actually made easier unfortunately by us having seen the actual label, and how the manufacturer's name and address is placed on the label. In other words, you know, the user looking at the device -- whose device would it be? So unfortunately it's a...

(Navine Irian): (unintelligible).

Loretta Chi: So I think unfortunately sometimes it comes down to us actually looking at the label which usually gets submitted through the UDI help desk. And I'm sorry I can't be more specific than that just based on your description.

(Navine Irian): Okay, and the other one is a tooth whitening company that basically takes - it's a private label company. So - and they sell cases of impression trays and materials and so forth. The original manufacturer is from - is not on the product whatsoever. It's only the private label manufacturer part number.

Loretta Chi: Okay. So once a private labeler puts its own brand on a device, they become the labeler.

(Navine Irian): Okay perfect. Thank you so much.
Coordinator: We want to thank everyone for all of your questions today. We do have several questions in the queue. So we will be ending the Q&A shortly, but we will take a few more until then. Thank you.

Loretta Chi: Okay, can I just say before - if we do run out of time, I encourage those who did not have a chance to ask questions on this webinar to submit their questions to the UDI help desk.

Coordinator: Thank you. Our next question comes from (Patricia Lee). (Miss Lee), your question is up at this time. (Patricia Le) or (Lee)?

(Sajit): Yes, this is (Sajit). Thanks for taking my call. I have a question about the GUDID account. I was sometimes back that we cannot register for the GUDID account until March. Is that still true? And how long does it take to get an account?

Loretta Chi: As I said before - well first of all, stay tuned for the next webinar which is Getting Ready for GUDID. Some of the GUDID questions will be answered then. Right now the GUDID is open to class three labelers and devices that are licensed under the Public Health Service Act.

We will be opening the GUDID to implant, life supporting, life sustaining devices soon, and then after that it will be opened up to the class two labelers. We don't have a date yet for the class two labelers, which is to say that I'm not aware of a March date.

Coordinator: Our next - sorry. Our next question comes from (Maryann Eggly). (Miss Eggly), your question is up at this time.
(Maryann Eggly): Thank you everybody for your time. My question is if I'm the manufacturer of a medical device that -- let's just call it device A -- and I manufacture device A, but I label it for several different contract manufacturers, do I have to have a separate DI for each company I manufacture that device on behalf of?

Loretta Chi: If I understand your question correctly, you're the contract manufacturer and you're manufacturing the device on behalf of other companies that are putting their brand on the device. Is that correct?

(Maryann Eggly): That's correct.

Loretta Chi: Right. And in each case, then the brand holder -- I'm just using this as an example. Say you're manufacturing a device and Fisher Scientific puts its brand on it, then Fisher Scientific becomes the labeler.

(Maryann Eggly): Be even though I am doing the physical manufacturing?

Loretta Chi: Yes. It's - the definition of a labeler is someone who causes the label to be applied to the device. Although you're actually putting the label on the device, it is the brand holder - excuse me - who is actually causing the label to be placed on the device.

(Maryann Eggly): Okay.

Loretta Chi: So they're actually causing you to put the label on the device.

(Maryann Eggly): Okay, great. That's great clarification. Thank you.

Anita Rayner: And to - this is Anita Rayner again. To add to what Loretta said -- and I guess it's obvious at this point that if a user picks up the device and looks at it in this
last case in this last example, and it says Fisher Scientific, and they look up the DI in the GUDID database, they're going to - the record that should be pulled up should relate to Fisher Scientific because that's what's on the label.

(Maryann Eggly): Thank you, but my - see, my concern was in the event, God forbid, that there's some kind of a manufacturing issue, wouldn't the information on the DI need to point all the way back to the actual manufacturer's last processor of that device?

Loretta Chi: That would be sort of the logic that you would think of, but you see, we're depending on the fact that you, when you ship the device to Fisher Scientific, are keeping the records of what you shipped.

(Maryann Eggly): Okay. So in the event of a recall and it goes back to Fisher Scientific, we're depending on Fisher Scientific to their -- for example hypothetically -- to then go back to whoever they had - whoever their contract manufacturer was to address the issue.

Loretta Chi: Exactly.

(Maryann Eggly): Okay. Great. Thank you.

Coordinator: Our next question comes from (Yi Chen). (Mr. Chen), your question is up at this time. And this may be our last question.

(Yi Chen): The question was answered in our last question, thank you.

Coordinator: Thank you, (Mr. Chen). Our next and final question then will be from (Jessie Jones). Your question is up at this time.
(Jessie Jones): Hi. Thank you for the overview on the UDI requirements. My question is if we are a manufacturer and we make device A, and then we make a variation of that same device for a different company, and then have, you know, we manufacture it for the brand of the other company, who is the labeler on record of the second device.

Loretta Chi: The brand holder. It's the same situation that we were talking about in the question before.

(Jessie Jones): Right. So - okay. So even if it's - everything goes back to me, it would be the brand holder who is required for all that labeling requirement even though it would eventually go back to me?

Loretta Chi: What do you mean by they would go back - what do you mean by go back to you?

(Jessie Jones): It goes back to me because I guess we would be providing them with all of these devices, and they really nearly - I think really distributing it, right? The entire system would be set up by us, and I guess they would - in my mind I feel that they would ask for our help on...

Loretta Chi: You may be setting up the system, you may be handling the compliance, but it's ultimately the brand holder who is responsible. So although you may be doing it, they are the ones that are responsible. So if it doesn't get done, they're the ones who are on, you know, they're held liable for complying.

(Jessie Jones): Okay. Thank you.

Irene Aihie: Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questions. If you were unable to submit a question this afternoon,
please submit your question to the UDI help desk at www.fda.gov/udi.

Recordings of today's webinar along with the slide presentation and transcript will be available at www.fda.gov/training/CDRHLearn by Friday, January 23 under the tab- Unique Device Identification System.

If you have additional questions about UDI or GUDID please use the contact information provided at the end of the slide presentation. As always, we appreciate your feedback. We will now take a 30 minute break before the start of our next presentation -- Getting Ready for GUDID -- presented by Indira Konduri.

Please feel free to stay on the line or disconnect and call back shortly. The presentation will begin promptly at 2:30 Eastern Standard Time, and the dial in number and passcode will remain the same. Thank you.

Coordinator: And this does conclude session one. Please disconnect all audio lines from the - or remain on the lines. At this time we will playing brief music on hold until session two. Thank you.

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