

FDA Webinar: Unique Device Identification: Convenience Kits Final Guidance

Moderator: Irene Aihie
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Coordinator: Welcome and thank you all for standing by. At this time all participants will be in a listen-only mode until the question-and-answer session at the end of today's conference. During the question-and-answer session if you do have a question you may use Star 1. Today's conference is being recorded. If you have any objections you may disconnect at this time. I would now like to turn the call over to Ms. Irene Aihie, you may begin.

Irene Aihie: Hello and welcome to today's FDA webinar. I am Irene Aihie of CDRH's Office of Communication and Education. On April 25 the FDA issued the Unique Device Identification Convenience Kit Final Guidance. The guidance provides clarity to device manufacturers on the marking of convenience kits with the unique device identifier, UDI.

A convenience kit contains two or more different medical devices packaged together for the convenience of the user. Today Christina Savisaar, Regulatory Policy Analyst and Loretta Chi, Senior Regulatory Counsel both from the Office of Strategic Partnership and Technology Innovation will discuss the final guidance.

Following the presentation we will open the lines for your questions related to information provided during the presentation. Additionally there are other Center subject matter experts to assist with the Q&A portion of our webinar. Now I give you Christina.

(Christina Savisaar): Hello. Welcome to today's webinar. This presentation is about unique device identification of convenience kits and the recently published final guidance on this topic. I am Christina Savisaar.

(Loretta Chi): And I am Loretta Chi.

(Christina Savisaar): Here is the agenda for this webinar, first we will briefly discuss the objectives of this webinar, provide a little background, describe the scope of the guidance and clarify some definitions. These definitions are important to the key policy principles which we will also outline in this presentation. Finally we will discuss shareholder considerations and we'll close by walking through some examples.

The objectives of this webinar are to familiarize you with the content of the unique device identification convenience kits guidance and to provide our current thinking on how the terms convenience kit and medical procedure kit should be applied for purposes of unique device identification.

(Loretta Chi): The objective of the unique device identification system is to adequately identify devices through distribution and use and to facilitate post-market requirements such as adverse event reporting and recalls. The UDI system will also enhance studies on device use to produce data that will help ensure safer and more cost-effective devices.

The UDI rule requires the label and package of every device marketed in the United States to bear a UDI unless an exception or alternative applies. Convenience kits is one of those exceptions that may apply.

If a device is a convenience kit, because remember all kits are devices, and the convenience kit label bears a UDI the individual devices are not required to be labeled with a UDI. Keep in mind that exceptions are not requirements. There is no prohibition against your labeling each device in a convenience kit with a UDI.

The draft guidance published in January 2016 and the final guidance published on April 26, 2019.

(Christina Savisaar): We responded to comments to the draft guidance document by narrowing the scope of the final guidance so that it does not apply to IVDs and combination products.

It is important to remember that the guidance that we just published is only intended to be applied for purposes of unique device identification and not for other regulatory purposes where the term convenience kit may be used.

Note that there is a guidance on convenience kits that was published in 1997. The purpose of the 1997 guidance was to reduce the regulatory burden on both the manufacturers and FDA by providing enforcement discretion when already cleared or exempted devices were being assembled into kits that permits finished devices that are packaged and labeled consistent with their pre-market authorization to be assembled into kits without the kit also needing pre-market authorization.

Although the 1997 document uses the term convenience kit, it does not necessarily align with convenience kit as we interpret UDI requirements.

(Loretta Chi): So (Christina) what is a convenience kit under UDI requirements?

(Christina Savisaar): I'm glad you asked. The UDI rule defines convenience kit as two or more different medical devices packaged together for the convenience of the user. We interpret this to mean a device that contains two or more different medical devices packaged together and intended to remain packaged together and not to be replaced, substituted, repackaged, sterilized or otherwise processed or modified before being used by an end user.

(Loretta Chi): Packaged together?

(Christina Savisaar): Yes packed, you know, wrapped or sealed in a single container and the labeler does not intend for the package to be unwrapped or unsealed before it is used by an end user.

(Loretta Chi): Oh. What's an end user?

(Christina Savisaar): An end user is someone who is using the device on a patient. An end user can be a caregiver, healthcare professional or the patient himself or herself.

(Loretta Chi): Okay. So I'm looking at this final guidance document, what's this about medical procedure kits? Are they convenience kits?

(Christina Savisaar): They may or may not be convenience kits for purposes of unique device identification. A medical procedure kit typically consists of one or more medical devices packaged together to facilitate a single surgical or medical procedure.

Whether or not a medical procedure kit is a convenience kit for purposes of unique device identification depends on whether it is a device and the devices in the kit are packaged together and intended to remain packaged together and not to be replaced, substituted, repackaged, sterilized or otherwise processed or modified before being used by an end user.

(Loretta Chi): So not every medical procedure kit is a convenience kit.

(Christina Savisaar): No and not only that, not every collection of two or more different medical devices is considered a convenience kit for UDI purposes.

Also keep in mind, as (Loretta) said earlier, the convenience kit exception is not mandatory. Like any other exception, you, the labeler, makes the decision on whether or not to utilize an exception that is applicable to your device. You are free to label the devices in your convenience kit with UDIs.

In fact, we encourage you to reach out to your customers to understand their preferences to inform your decision-making on how you will label your convenience kits.

Further when you are submitting the data on the convenience kit to GUDID it will be helpful for your customers to know what devices are in your convenience kits by including the list of devices and the device description of your DI record.

(Loretta Chi): We realize the interpretations in this guidance means that there are some devices that labelers thought were convenience kits that may not be and this could impact the manufacturing processes.

If you think your processes may be adversely impacted and you have an alternative that will achieve the objectives of the unique device identification system you may request FDA consider that alternative.

(Christina) do you think it would help if we gave some examples?

(Christina Savisaar): I think it would (Loretta).

(Loretta Chi): Okay so let's start with a first aid kit sold at retail. Now this particular first aid kit contains only medical devices because if it contained drugs then it would be a combination product and that is outside the scope of this guidance.

So we have this first aid kit that is sold at retail, has two or more different models or versions of devices, packaged together and intended to remain packaged and not replaced, substituted, repackaged, sterilized or otherwise processed or modified before being used by an end user. Is that a convenience kit?

(Christina Savisaar): Yes (Loretta). A retail first aid kit as you have described on the previous slide is a convenience kit. This means that the convenience kit exception under 21 CFR801.30-(a)(11) can be applied by the labeler. And if the label affixed to the immediate container of the kit bears a UDI the label of each individual device within the container is not required to bear a UDI.

Note the end users who have purchased the retail first aid kit may choose to purchase other devices to augment or replenish the first aid kit. Labels and packages of replenishment devices should bear a UDI, unless of course another exception or alternative applies, because these are not considered part of the convenience kit.

Can we try another example to see if it aligns with the interpretation in the guidance?

(Loretta Chi): Okay.

(Christina Savisaar): This one is a non-sterile orthopedic device set. It is a collection of non-sterile implants and reusable instruments that are intended by the labeler to be cleaned and sterilized prior to use.

They are placed in sterilization trays and in a surgery a subset of implants is removed and selected for use. At the end of the case the instrumentation, the unused implants and implants to replenish those that were used during the surgery are placed into the sterilization tray to be cleaned and sterilized for potential use in a future surgery. Is this a convenience kit?

(Loretta Chi): No (Christina) it's not. It does not align with the interpretation of the guidance because the devices are intended to go into go cleaning and sterilization prior to each use. Each device must comply with applicable UDI labeling, data submissions and direct mark requirements. Ready for another example?

(Christina Savisaar): Yes.

(Loretta Chi): Well this medical procedure kit is sterile. It contains two or more models of a device sealed in a single container and all those devices whether or not they're used in a single procedure on a single patient for whom this kit is intended are disposed of after the procedure. Is this a convenience kit for purposes of UDI?

(Christina Savisaar): Let's see, it's a device comprising two or more different devices. It is packaged together and intended to remain packaged together without

replacement, substitution, repackaging, sterilization or any other processing or modification before being used by an end user. It is a convenience kit.

The next example is a little different. Like the previous example it contains two or more models of devices sealed in a single container all of which is supplied sterile. The devices are suture and stainless steel instruments. After use by the end user, during which the suture is consumed, the instruments may be reprocessed and reused. Is this a convenience kit?

(Loretta Chi): Yes (Christina) it is. Note that the devices in the kit intended to be used more than once and intended to be reprocessed are subject to direct marking under 21CFR801.45.

Here is our last example. A labeler manufactures a number of different models or versions of teething rings in varied shapes. The labeler packages one teething ring of each model together in a fixed quantity to create an item for retail so that when they're grouped together they have a higher profit margin and it allows each end user to select to use a particular teething ring. Is this a convenience kit?

(Christina Savisaar): I want to make sure I understand. For purposes of this example is the assumption that the labeler has not created a device in the creation of this package?

(Loretta Chi): You may assume that.

(Christina Savisaar): If the devices packaged together are not collectively a device then this example is not a convenience kit for purposes of unique device identification.

Since UDI applies broadly to medical devices we sometimes get questions about whether a product is a device. Determining whether a product is a device is outside the scope of the UDI program. We refer these questions on. And so this example does not get into these specific details that would go into this determination.

It is not always obvious to a manufacturer whether or not their product is a device. As noted in the guidance if you are uncertain about whether your collection of two or more different devices meets the definition of a device please contact CDRH's 510K program or CBER's Office of Communication Outreach and Development.

(Loretta Chi): So we are at the close of the presentation. This slide provides information on where you can find the unique device identification convenience kits guidance and the link to the UDI help desk if you have questions on this or other UDI topics.

(Christina Savisaar): The Division of Industry and Consumer Education is also available to answer all questions about medical devices. At this point we will now be taking question from the audience.

Irene Aihie: Operator are you there?

Coordinator: Yes I'm here. Thank you we would now like to open the lines for any questions. If anyone does have a question on the phone please hit Star 1 and record your name when prompted. Again that's Star 1 to ask a question on the phone. One moment while we wait for the first questions.

(Christina Savisaar): Before we go to the questions on the phone I'd like to start off with a question that we have gotten from stakeholders since this guidance issued.

The scope of the guidance clearly states that it does apply to IVDs. (Loretta) does this mean that IVDs cannot be convenience kits?

(Loretta Chi): No that's not what it means. What we said in this guidance document is that the guidance document does not apply to [IVDs] and combination products. That means that whatever the law or the policy was prior to the issuance of this guidance still remains in effect.

We can now turn to questions from the audience.

Irene Aihie: Operator we're ready for our first question.

Coordinator: Thank you I was just getting the name for you. The first question is coming from (Karen Lou), your line is open.

(Karen Lou): Hi there can you hear me?

Irene Aihie: Yes we can.

(Karen Lou): Perfect I have a question about the sterilization aspect of a convenience kit. I'm having trouble understanding if I'm combining two devices packaged together and then they're not yet sterile when I package them together but then I terminally sterilize them and then I ship them to the end user. Does that still qualify as a convenience kit?

(Loretta Chi): Let me make sure I understand, you're asking that the package - the devices packaged together are intended to be sterilized by the end user?

(Karen Lou): No they're terminally sterilized by the manufacturer and then shipped to the end user who doesn't have to do any further processing or anything.

(Christina Savisaar): If they just open the package and use the devices it sounds like it's a convenience kit for purposes of unique device identification.

(Karen Lou): Okay great thank you for clarifying that.

Coordinator: Thank you next we have (Alfred Litlock), your line is open.

(Alfred Litlock): Thank you very much. I have a pneumatic drill and a hose that's in a tray that is sterilized by the hospital each time it's used. I assume since it is sterilized by the hospital it would not be a convenience package. Is that correct?

(Loretta Chi): That's correct.

(Alfred Litlock): Thank you.

Irene Aihie: We'll take our next question.

Coordinator: Thank you next we have (Darren Summer), your line is open.

(Aaron Summer): Hi (Aaron Summer). We make convenience kits for (unintelligible), for (unintelligible) monitoring. They're really only medical device we have in there is electrode. The rest is batteries, alcohol wipes, scrubby pads. Is this a kit that would need - that would be required to use UDI as well?

(Loretta Chi): Wait a minute, I don't understand the question. Are you asking - convenience kit means as the devices (unintelligible) in - if your device qualifies as a convenience kit. The individual devices do not have to be labeled with a UDI but the kit itself does.

(Aaron Summer): It does okay.

(Loretta Chi): Yes all kits must be labeled as a UDI.

(Christina Savisaar): It did sound if you were including an alcohol wipe there it might be a question of whether it's a combination product or not. So there are considerations such as that.

I think you also mentioned that there were things in the package that were not devices at all. We sometimes get questions about this, like if somebody has an electrode prep kit and they have two or more medical devices and they otherwise meet the definition of a convenience kit but then they also include a razorblade for shaving or something like that.

We don't - just to be clear -- we don't expect the UDI to be assigned to any non-device items. The requirement applies to medical devices.

(Aaron Summer): (Unintelligible).

(Loretta Chi): (Unintelligible) that. Basically a kit has to have a UDI and if it qualifies as a convenient kit then the individual devices are not required to have a UDI. Non-devices are never - anything that is not a device, UDI only applies to medical devices so if it's not a device then the UDI requirements don't apply.

(Aaron Summer): Okay so the electrode itself (unintelligible) would make it apply then.

(Loretta Chi): Well the way you described it, it really sounded like the whole thing was a kit and yes the UDI has to be on the kit but not necessarily on the individual devices.

(Aaron Summer): Okay (unintelligible).

(Loretta Chi): But I can't tell whether this is a convenience kit or not quite frankly.

((Crosstalk))

(Aaron Summer): ...it is. So we have electrodes, we have alcohol pads and we put it - we sealed them in one bag. And then we usually do the UDI label on that bag and then also UDI label on the box that comes in the kits 20.

(Loretta Chi): Tell you what, we have a help desk. Just to make sure that we have all the facts that we need before giving you an answer do you mind...

(Aaron Summer): Okay.

(Loretta Chi): ...sending a questions just through the help desk.

(Aaron Summer): Yes I can do that.

(Loretta Chi): Thank you.

(Aaron Summer): Thank you.

Coordinator: Thank you next we have (Eric Carey), your line is open.

(Eric Carey): Yes hi I have a question. We have a first aid kit with, let's just say Band-Aids, gauze pads and non-latex gloves. If I was to now add aspirin to that kit what would my UDI requirements be?

(Loretta Chi): Well that would be a combination product and that is outside the scope of this particular guidance document. And that's what the purpose of this webinar is. If you'd like to know what the UDI requirements are for combination products I suggest you submit that to the help desk and we can respond to that question there.

(Eric Carey): Okay so that one then, that was shifted to a combination. So then you can't (unintelligible).

(Loretta Chi): Yes so when you add a drug it becomes a combination product.

(Eric Carey): Okay and you don't have any information on whether that needs UDI or not?

(Loretta Chi): Oh I have information but that is outside of this webinar that's why I'm saying that I would prefer if you submit it through a help desk so that we can answer it separately.

(Eric Carey): Okay thank you.

(Loretta Chi): Sure.

Irene Aihie: We'll take our next question.

Coordinator: Thank you next we have (Steve), your line is open.

(Kirk Gonna): Hi there (Kurt Gonna) here with (Ecolab). We've got a question on these convenience kits. So we've got one kind of kit that has a single medical device in it along with a bunch of non-medical devices packaged together. It's a non-sterile kit.

The item that's the medical device can be labeled with the UDI and not the kit. Does that make sense?

(Loretta Chi): Yes.

(Kirk Gonna): Okay.

(Loretta Chi): Yes it makes sense. What is your question?

(Kirk Gonna): Question is do we have to have the external label on the UDI kit or do we have to have the UDI label on the kit level or...

(Loretta Chi): The definition of a kit is one or - two or more different devices packaged together.

(Kirk Gonna): Yes so it's not...

(Loretta Chi): So if you only have a single device it's not a kit.

(Kirk Gonna): Right okay so the UDI would have to be only on the medical device in that instance and it cannot (unintelligible)...

(Loretta Chi): Well it would have to be on the label of the device wherever the label is. So if you have the label on the device itself then that's where we'll see it. If the label is actually on the outside package of the device somehow then it would be there.

(Kirk Gonna): Yes understood. Now then on our other kind of kits and that first - actually both of these are Class 1 devices so on that front what are we looking at in terms of the implementation timing for those UDI requirements?

(Loretta Chi): If you go to our Web site you'll see under, what is it, our Web site just changed completely so I'm not as familiar with the Web site as I used to be, and literally changed last week.

So I believe there though if you go to Extensive Alternative Timeframes, Timelines, something like that, you'll see the timelines for Class 1 devices. The compliance date was actually 2018 but we issued an immediately in effect guidance document that effectively - okay I'm going to not be a lawyer right now...

(Kirk Gonna): Sure yes.

(Loretta Chi): ...basically for all intents and purposes your compliance date is September 24, 2020 for the UDI label and data submission requirements not direct marketing. Direct marketing is, what, 20...

(Christina Savisaar): 2022.

(Loretta Chi): 2022.

(Kirk Gonna): Okay appreciate that help and appreciate this seminar, thank you.

(Loretta Chi): Sure.

Coordinator: Thank you next we have (Zulayka), your line is open.

(Zulayka): Hi (Zulayka). My questions is around first aid kits. So we assemble first aid kits containing only sterile devices such as Class 1 gauze pads, rolled gauze,

non-adherent pads. My question is around the - when we submit to GUDID concerning the question device packaged as the sterile.

So we received this Class 1 devices from our supplier already sterilized and we assemble into the first aid kit and send to our customer...

(Loretta Chi): Okay so I just want to make sure because (Varsha) here who's probably going to answer the question who's looking a little puzzled. I just want to make sure, the entire package is sterilized or just the individual devices are supplied sterile?

(Zulayka): The individual devices are supplied as sterile.

(Loretta Chi): But the package itself is not sterilized.

(Zulayka): It is not sterilized, you're correct.

(Loretta Chi): So is it supplied - do you know?

(Zulayka): Hello?

(Varsha Thakar): Yes you should mark as - it to - yes. (Unintelligible) yes.

(Zulayka): So device packaged as the sterile the answer for that would be as a yes?

Woman: Yes.

(Zulayka): Okay and my additional question is in this case as well, the first aid kit as all the individual devices they are classified as a Class 1 and the kit itself as well

is a Class 1 device under the FDA code that we have classified. That case the UPC will serve as the UDI. The rule would apply?

(Christina Savisaar): Yes.

(Zulayka): Okay all right thank you very much.

Coordinator: Thank you next we have (Augustine), your line is open.

(Augustine): Yes my name is (Augustine) thank you and I just had a question about Slide 21. I don't know if it's possible for you to go back but it was one of the examples and I just had a question. I think if you could kind of go into a little bit more explanation as to why that is a kit.

(Loretta Chi): I'm sorry which example is that?

(Augustine): It's example Number 4 and it says a sterile kit containing both single-use and reusable medical device packaged together.

(Christina Savisaar): Another key factor here is it's supplied sterile. So like the other examples that are convenience kits when it is received it can be used - opened and used immediately without modification or processing, sterilization.

(Loretta Chi): The definition of a convenience kit is two or more different devices that are packaged together and intended to remain packaged together and not be in any way - the individual devices are not to be replaced (unintelligible), repackaged, et cetera, et cetera. And that applies to this particular kit because it is supplied sterile.

(Augustine): Okay.

(Loretta Chi): And the devices both the single-use and the reusable medical devices originally are intended to be packaged together and for the first time not used until it is at the point - not to be opened until it's at the point of use. Consequently...

(Augustine): Okay thank you.

(Loretta Chi): ...the reusable medical devices will be reprocessed and that, therefore the direct market requirement applies to them.

(Augustine): Okay that's (unintelligible) okay thank you very much.

(Loretta Chi): Sure.

Coordinator: Thank you next we have (Pat Carter), your line is open.

(Cat Crowder): Hi this is (Cat Crowder). If as a result of this guidance we have identified that something we thought was a convenience kit is not a convenience kit what is the time period that we need that we have in which to rectify the situation?

(Loretta Chi): What kind - what class device are you?

(Cat Crowder): I haven't actually done the investigation yet but it's a Class 2s.

(Loretta Chi): Well the Class 2 compliance date was 2016. So my suggestion is that you try to get your device into compliance as quickly as possible.

(Cat Crowder): Right (unintelligible) we...

(Loretta Chi): I can't tell you - I mean I can't tell you when the investigator - I don't know what the timeframe is for investigators to - I don't know what their work plan is I'm sorry.

(Cat Crowder): (Unintelligible) I understand...

(Loretta Chi): I can't predict how soon somebody would find out if they're not in compliance and...

(Cat Crowder): There hasn't been advice to remove from the market...

(Loretta Chi): I wouldn't remove them from the market because you can do corrections by issue - by in some way putting the barcode on the - I don't know.

(Christina Savisaar): I would say, you know, just to remind everybody, final guidance is non-binding, recommendation by the FDA. We're telling you how we think you should do this and we do take into account factors that, you know, this is a new program people are implementing UDI.

If they follow their rationale and how they decided to label things and later found out it was counter to what we were recommending or for that matter counter to what their end users needed, it needs to make a change.

We do see that happen where people are allocating DIs differently to devices they might have thought they needed one for and then they come back and make changes to records and make changes to their labeling and document, you know, that decision-making...

(Cat Crowder): Okay.

(Christina Savisaar): ...in their records.

(Loretta Chi): (Unintelligible)...

((Crosstalk))

(Loretta Chi): ...don't think okay that doesn't mean you don't have to be in compliance, you do.

(Cat Crowder): Absolutely (unintelligible).

(Loretta Chi): Just don't panic.

Coordinator: Thank you next we have (Young Jing), your line is open.

(Young Jing): Hello yes this is a question about the kind of software-related. So we have an electronic medical device with has UDI label and the device contains another standalone software device internal and it has separate classification. Is this effectively a convenience kit by itself since we have two device together?

(Loretta Chi): I don't believe this is a convenience kit because I don't think that the devices are packaged together intended to remain packaged together until used by the end user. I think it's more like a - either a system or...

(Christina Savisaar): Could be a kit but doesn't qualify for a convenience kit...

(Loretta Chi): ...a convenience kit.

(Christina Savisaar): ...exception because often software is separated to be installed.

(Young Jing): Okay yes that's helpful thank you.

Coordinator: Thank you next we have (Elizabeth Proctor), your line is open.

(Elizabeth Proctor): Hi we have multiple Class 2 devices that we label individually with UDIs and sell them individually but we also sometimes package them together in a bag and that bag receives a new item number. So we're wondering does that bag with the new item number need a UDI or can we just ship it out with all the individually labeled items?

(Loretta Chi): So this is a standard packaging configuration?

(Elizabeth Proctor): Yes it is. It's something we would stock.

(Loretta Chi): Okay would you say that it's closer to example where - Example 3 or 4 or closer to the Example 5 is the teething ring? Is it (unintelligible)...

(Elizabeth Proctor): No they're definitely all different Class 2 devices inside.

Woman: And they're not sterile.

(Elizabeth Proctor): And they're not sterile. But, you know, people can either buy them individually or they can buy a bag of the various devices...

Woman: Various, it's not all the same.

(Elizabeth Proctor): It's not always the same, that's various. That's (unintelligible).

(Loretta Chi): (Unintelligible) are the devices intended to be used together or do they have some related intended use or are they just completely separate?

Woman: For patient setup kit.

(Elizabeth Proctor): It's like a respiratory patient setup kit. So yes then it's typically be used...

Woman: (Unintelligible).

(Elizabeth Proctor): ...the same time.

Woman: Yes.

(Elizabeth Proctor): The cannula oxygen tubing.

((Crosstalk))

(Elizabeth Proctor): ...a packaging level needing a UDI or is it just a bag?

(Christina Savisaar): Well if your collection of things is creating a device, you know, it has a common medical intended use and you determine that then it could potentially be a convenience kit. But keep in mind under 801.20 device packages also require a UDI.

So if it - even if it's not a kit because the collection is not a device it may require UDI because it's a device package and it's being supplied in a standard configuration of fixed quantity of devices.

(Loretta Chi): But isn't the UDI (unintelligible) different for device packaging as opposed to a kit? Isn't the UDI - the assignment of UDI should be related to the primary DI.

(Christina Savisaar): When it's an assorted package with multiple models and versions it could still be a device package.

(Elizabeth Proctor): So it's the packaging level basically that requires a UDI.

(Loretta Chi): It does but I suggest that you contact the UDI help desk because there are different ways in which you assign the UDI depending on whether is the device package under 801.20 or whether it is the kit.

(Elizabeth Proctor): Okay thank you.

Coordinator: Thank you next we have (Nupor), your line is open.

(Nupor): Hi thank you for giving me the time. So I have a question about a device that we basically have implantable Class 3 device which is a stent. And then we offer few choices of compatible catheters that when ordered by the physician we can send it as per the permutation or the choice of that physician. So what do you think our UDI strategy should be?

(Loretta Chi): So every shipment's different?

(Nupor): So we have, like, a list of five catheters which are compatible with this device, implantable device and we sell it in a box of two catheters or three catheters with that stent. So all of these are sterile devices. They are non-reusable. So I'm confused whether it is a convenience kit or it can be a kit which is basically termed as medical procedure kit.

(Loretta Chi): (Unintelligible) okay start all over again. So a doctor is ordering the stent.

(Nupor): Yes.

(Loretta Chi): And then the doctor orders one or more catheters.

(Nupor): Yes (unintelligible).

(Loretta Chi): But the doctor is ordering that separately, not necessarily as a - you're not packaging them together and selling them together as a standard package.

(Nupor): No we (unintelligible)...

(Loretta Chi): (Unintelligible) waiting for the doctor to tell you what the doctor wants. They want the stent and then they want something else but they may not want anything at all, they may just want the stent.

(Nupor): No they either have a choice of two catheters or three catheters, that's it. They don't get to only order the stent. Hello?

(Loretta Chi): Yes no we're thinking.

(Nupor): Okay sorry.

(Loretta Chi): I don't think it's a convenience kit.

(Nupor): Okay.

(Loretta Chi): Because it's not standard package. But I'm not sure if it's a shipping container either.

(Nupor): We do send it out as a kit though.

(Loretta Chi): Well you send it out as a package for order.

(Nupor): Yes.

(Loretta Chi): So if, like, they order two different items.

(Nupor): Yes.

(Loretta Chi): And they each have their own separate UDIs and they have their own separate catalog numbers of other types of internal...

(Nupor): Yes (unintelligible).

(Loretta Chi): ...identification.

(Nupor): Yes they do because the catheters specifically are also, you know, separate devices which can be sold separately but it's not really this. But for these particular projects and this particular manufacturing facilities (unintelligible) them and they sell them as kits.

(Loretta Chi): Okay so you're not really selling them as kits. It's more like Amazon.

(Nupor): Yes.

(Loretta Chi): You go to Amazon and you order different items and they put it in a box and they ship it.

(Nupor): Yes exactly.

(Loretta Chi): (Unintelligible) more like that.

(Nupor): Yes it is (unintelligible).

(Loretta Chi): Then that's a shipping container. That does not require a UDI.

(Nupor): Got it, okay. Okay thank you so much this was really helpful.

(Loretta Chi): But the individual devices have to have a UDI.

(Nupor): They do.

(Loretta Chi): Okay.

(Nupor): Okay thank you.

Coordinator: Thank you next we have (Barbara Shwedenbeck), your line is open.

(Barbara Shwedenbeck): Hello I was wondering what technically is considered a different medical device. For example a variety package of tampons where you get super and regular packaged together.

(Christina Savisaar): The - we're referring to a different model or version of device. In the final UDI rule there is some discretion given to the labeler to determine what, you know, they consider to be under the same set of specifications and what they consider to be a different version or model.

The definition in 801.3 is that version or model means all devices that have specifications, performance, size and composition within limits set by the labeler.

(Loretta Chi): So basically it's up to you the labeler to decide whether you have different - if it constitutes different version or models of the device.

(Barbara Shwedenbeck): Okay say I did consider them to be different models or versions and tampons have different specifications in terms of absorbency per the CFR.

(Loretta Chi): Yes.

(Barbara Shwedenbeck): Then would that be considered a convenience kit?

(Christina Savisaar): It sounds like it would be - it could be a device package. Again if it was a convenience kit the combination would have to be a device so the combination itself would have to constitute a device and there are circumstances of intended use claims or things different than the regular intended use of the individual devices that could put that one way or another but...

(Loretta Chi): Kind of grey but I would say it's close to being a convenience kit, pretty close.

(Barbara Shwedenbeck): Okay thank you.

Coordinator: Thank you next we have (Jason Lion), your line is open.

(Jason Lion): Hello and thank you for taking my call. This is just a question of understanding terms in the guidance document itself because the word or the acronym UDI is for Unique Device Identifier and yet in one of the question and answer section on Page 6 it actually says Device Identifier. Are you using those terms synonymously?

(Loretta Chi): Are we using the terms, I'm sorry?

(Christina Savisaar): Do you mean a unique...

(Jason Lion): Are you using those terms - are you using UDI and DI synonymously?

(Loretta Chi): No we're not. A UDI is the - both the device identifier, the DI and the PI. If we said DI then we were probably talking about the device identifier which is one portion of the UDI. I don't have the guidance in front of me so I don't know the context of which you're quoting.

(Jason Lion): It just says how much variation's allowed for -- this is Question 2 on Page 6 of the guidance document -- it says how much variation is allowed for different convenience kits to be identified by the same device identifier, DI.

(Loretta Chi): Yes.

(Jason Lion): If I substitute one device for another will the kit need a new DI?

(Christina Savisaar): The device identifier identifies the model or version and then the UDI also incorporates production identifiers that are - the DI portion of the UDI is static for a particular model or version but the PIs of you generate UDIs for devices you are producing that, you know, the expiration date is changing or the lot or batch is changing. The PIs change overtime.

(Jason Lion): Okay yes this is - I think it's in reference to changing out a - like if you have a kit put together and then you decide to alter that kit by maybe substituting one device with another device it seems to me that the DI would change but I'm wondering if the UDI would change also because of that change.

(Loretta Chi): Well the UDI would naturally change if the DI changes. The question is that...

(Jason Lion): Okay.

(Loretta Chi): ...if your version or model does not change the UDIs could still change because the production identifier will change. For every production batch or so forth that the device goes through, each production lot or batch will have a different UDI because the PI portion will change but the DI portion won't change because the version or model hasn't changed.

(Jason Lion): Okay great thank you very much.

(Loretta Chi): Sure.

Coordinator: Thank you next we have (Robin), your line is open.

(Robin): Hi I had a quick question here. So we have four devices, each device has its separate item number, a separate model number and a separate UDI. All four devices are going into a, basically a corrugated box under a new item number. Is that considered the convenience kit and would it require a UDI? And three of those pieces are our partner's components, not our components. Hello?

(Christina Savisaar): Hi I think it's difficult to determine whether it's a device package or a convenience kit because that factor of are the four things you put together a device or not. It's is a key piece of information that would change the answer to that question.

(Loretta Chi): Yes I didn't perfectly understand the question, I'm sorry. Do you want...

(Robin): Okay so we have a...

(Loretta Chi): Oh go ahead.

(Robin): No go ahead I'll listen.

(Loretta Chi): No if you can rephrase the question that'll be great.

(Robin): Okay so we have four, basically four devices, one's a pump right, and then which we own and then in - we have a meter strips and lancets right which our partner - belongs to our partner.

All the pieces all have their own individual UDIs right. They all have their own item numbers, their own model numbers. But we're kitting them - well we're kitting them basically into a corrugated box with a new item number to make it easier for the end user or the customer care people to order. Would that corrugated box require a UDI?

(Loretta Chi): Okay there are - a convenience kit there's a - a convenience kit is a subset of a kit. And it sounds to me like you're putting together a kit. May or may not be a convenience kit but it certainly sounds like a kit and a kit is a device which requires a UDI.

It doesn't matter what type of packaging you use. That's not relevant. The fact that you're packaging it together at all and it's, you know, these are devices under tends to be having a common intended use. In some way they are intended to be used together (unintelligible) as a kit and therefore would require a UDI.

(Robin): Perfect because I put a UDI on it and I just wanted to make sure I did the right thing, okay thank you.

(Loretta Chi): You're welcome.

Coordinator: Thank you and again if there are any questions on the phone please use Star 1. Next we have (Stacy Cashmar), your line is open.

(Stacy Cashmar): My question was also about the definition of different medical devices so that's already been asked and answered, thank you.

Coordinator: Thank you (Stacy). (Alfred Litlock) your line is open.

(Alfred Litlock): Yes my question's also been answered thank you very much. Hello?

Coordinator: All right...

(Loretta Chi): Thank you.

Coordinator: Next we have (Sam), your line is open.

(Sam): Hi thank you so much for taking my call. Our company manufactures orthodontic brackets and we have a magnitude of brackets that we sell individually to the end user or to a dealer who sells to the end user and on certain cases we'll receive requests from our customers for custom configuration kits.

So depending on the prescription that the doctor assigns to the patient and the tooth angulation, et cetera, they will take - they will want to pick specific brackets to put together for the course of the treatment for a patient.

Now would that be considered a convenience kit because all of the devices are going to be - they will remain packaged together until utilized or used by the end user but they are a custom configuration per se.

(Loretta Chi): Well they're custom configuration in the sense that the orthodontist has chosen and selected each device that's going to be shipped together correct?

(Sam): Correct yes...

(Loretta Chi): It'll change from patient to patient.

(Sam): Correct but the device itself is not customized. We sell the device regardless of if the doctors requests that particular prescription or not. They're just choosing the configuration for the kit and then we're creating a new SKU. And my thoughts are that it would be considered a convenience kit but we just wanted confirmation (unintelligible)...

(Loretta Chi): But the problem with considering each one to be a convenience kit is that what - okay I'll tell you what we don't want. What we don't want is you to assign a new DI for every configuration because then you'll be submitting to...

Woman: (Unintelligible).

(Loretta Chi): ...GUDID...

(Christina Savisaar): It's a lot of records.

(Loretta Chi): ...and it'll be a lot of records and that's not going to be useful to anybody.
And so...

(Sam): That's what we're worried about.

(Loretta Chi): Yes don't do that. Please don't do that. We would prefer you either consider that to be like a shipping, you know, a unique order each time or you consider all of these configurations together to be a single device, a single version or model of the device. And then you would make the distinction by the PI, you know, the lot or batch or whatever.

(Sam): Okay (unintelligible)...

(Loretta Chi): Does that make sense?

(Sam): Even though there can be countless configurations of different kits (unintelligible) different devices...

(Loretta Chi): All right well...

(Sam): ...going into one kit.

(Loretta Chi): I wouldn't call - first of all I wouldn't call them kits necessarily. I'm not sure that they are kits because each one is so different. A kit is generally something that is a standard - is a device that the manufacturer or labeler produces continuously, the same thing over and over and over again. You don't do that. You have a different configuration for every patient...

(Sam): It can be yes.

(Loretta Chi): ...and that's not really a kit.

(Sam): Okay.

(Loretta Chi): Because you don't have a standard version or model.

(Christina Savisaar): You would have to put specifications around it. We do have records that you can find if you go to Access GUDID and do a little searching where people have, not what we would call custom, but a customizable device.

And when they describe their device description and how they've assigned the version or model it gives the parameters on what their specifications are, may contain one or two or three of these and, you know, one of these four things and two of these things based on the order of the healthcare professional. And that DI broadly covers the customization of the device.

And, like (Loretta) said, the production identifiers would be the one - would be the way that you could trace it to this is the one Dr. Jones ordered for...

(Sam): I see.

(Christina Savisaar): ...Patient A and this is the one Dr. Smith ordered for Patient B.

(Sam): I see because each item that would be - each item that's going to the doctor would be its own unique device. Like, and they could vary from Class 1 to Class 2.

So that's why we're trying to make sure we lock this down our understanding so that we're assigning for the upcoming kits that are - or not kit if it's not a kit but for the upcoming configurations that are Class 1s if we're going to have

to register per each, in quotations, kit that we're doing that appropriately (unintelligible) device.

(Loretta Chi): What do you mean by register?

(Sam): So each item that's in this assembly is a, within its own right, is a device on its own that we manufacture and we sell. So the doctor may be requesting this configuration but we may sell this configuration again if that configuration is requested by someone else if that makes sense.

(Loretta Chi): Well do you - I mean does it have a catalog number or a part number or is it - do you advertise it. I mean...

(Sam): It would...

(Loretta Chi): ...or is it just so happens that another doctor asks for the same order?

(Sam): Asks for the same order would be the scenario.

(Loretta Chi): But how would you keep record? Would you...

(Sam): It's (unintelligible)...

(Loretta Chi): I really think that it's just happenstance...

(Sam): It's a nightmare but we have been keeping record of it. It's just we're trying to understand...

(Loretta Chi): Okay I'm going to say again what we do not want is for every single configuration to be assigned a DI and then you should submit a DI record and GUDID for every single configuration under the sun.

(Sam): Okay.

(Loretta Chi): That would not be productive or constructive or useful to anybody. Not you because you have to pay all this money to get it done and not to GUDID because we have a lot of records and not to the patients because they wouldn't know what to do with all that information.

So if there's any way you could consolidate your DIs into, you know, at the very least, broad categories of kits or devices...

(Sam): Okay.

(Loretta Chi): ...I think everyone would appreciate that.

(Sam): Okay that's helpful I appreciate the elaboration.

(Loretta Chi): Okay.

(Sam): Thank (unintelligible).

Coordinator: Thank you next we have (Clyde Dotten), your line is open.

(Clyde Dotten): Hi if I understand correctly a Class 2 non-sterile individual device that is identified uniquely by an individual UDI, if it's packaged together with other items or medical devices that are UDI the overall package does not require a UDI assignment correct?

(Loretta Chi): No that's not correct.

(Clyde Dotten): Okay.

(Loretta Chi): It depends on why you packaged them together. It depends on whether...

(Clyde Dotten): They're sold...

(Loretta Chi): ...the...

(Clyde Dotten): They're sold to an individual or a dealer and it's sold as a package. So if the individual items in that package have unique UDIs because they can be sold individually does the overall package require a UDI assignment?

(Loretta Chi): It may. It depends on why you've packaged them together.

(Clyde Dotten): Because they have to be used as a system.

(Loretta Chi): Well then you definitely need to have a UDI on the package.

(Clyde Dotten): On the overall package.

(Loretta Chi): Yes.

(Clyde Dotten): Okay so even though they individual items have its own unique UDI assignment.

(Loretta Chi): Correct.

(Clyde Dotten): Okay thank you.

Irene Aihie: We'll take our next question.

Coordinator: Thank you (Liz Vo), your line is open.

(Liz Vo): Hi so I have - I think I have a pretty good understanding of what the convenience kit is. What if it's a component of a system and it's a software package and maybe other reusable devices and you want to sell them as a kit. Would that require a UDI?

Man: (Unintelligible).

(Loretta Chi): Yes I mean if all the various constituents together creates a device it requires a UDI.

(Liz Vo): But it's not, like, individually they're not a medical device. Like, say, you know, a software package, you know, it's not a medical device in and of itself. It has to be installed to a system...

(Loretta Chi): Well the components - constituents together to create a device do not individually themselves have to be a device to create a device, right. I mean you could have something that is not considered as a device and then you have something else that is not considered a device but you put them together and it's a device. Then it's a device so it needs a...

(Liz Vo): But what if it's not...

(Loretta Chi): ...UDI.

(Liz Vo): So I mean together they're not a device that needs to work with a system that's packaged separately. It's not going to be part of this kit. So is this kit - do you still consider this kit a device but it requires a UDI?

(Loretta Chi): You know, can you send this to help desk.

(Christina Savisaar): Yes I think this is specific (unintelligible)...

(Loretta Chi): I think - yes I think there's some factor that we need to explore a little bit more.

(Liz Vo): Okay.

(Loretta Chi): Thank you.

(Liz Vo): Okay all right thanks.

Coordinator: Thank you next we have (Karen) your line is open.

(Karen): Yes thank you very much. I am calling to ask we make both Class 1 and Class 2 devices and they're first aid-type kits. Do we have to have a unique - a UDI for each color of the bag that we put those first aid kits in?

(Loretta Chi): That depends on whether you consider each color a different version or model of the device.

(Karen): All the...

(Loretta Chi): (Unintelligible) we would like it if you did not but...

(Karen): Right that's what I was getting before when you said to kind of consolidate and use broad descriptions. So the items inside these bags are exactly identical but sold in a different colored bag.

(Loretta Chi): I will tell you this that I don't know who your issuing agency is but your issuing agency may have standards that you have to follow. Your issuing agency may have standards which you may need to follow which may require you to have a different DIs for each version or model - for what you may not consider is a version or model but they may.

But honestly we as FDA would prefer that you did not consider them version or - different versions or models but you have to check with your IA too.

(Karen): Okay and when you say issuing agency will you please define that.

(Loretta Chi): Well there are three - you are required to use the system, one of three FDA-accredited issuing agencies and they are...

(Karen): Oh okay.

(Loretta Chi): ...they are listed in the FDA Web site.

(Karen): I understand now yes okay. Okay well thank you very much.

(Loretta Chi): Sure.

Coordinator: Thank you next we have (Davia), your line is open.

(Davia): Hi can you hear me?

(Loretta Chi): Yes.

(Davia): Okay so I have a very similar question to the gentleman who asked prior to this where I have a 2 Class, two medical devices which can be individually sold. They both have individually a UDI on them. But we have a configuration under a separate part number where they are bundled together.

So my question was do we need a separate UDI for this when we bundle it together? It sounds like that answer to that is yes based on the previous answer. Did I get that right?

(Christina Savisaar): Yes.

(Davia): And then I guess my - the second part of my question is if the part number where we bundle together is a separate UDI does that UDI number have to now show up in the lower level two products as well or can they have their own separate UDIs?

(Loretta Chi): That is a packaging configuration question that - I - that's a little bit out of my area.

(Christina Savisaar): I see - what you're talking about is that each of your two items has a label with a UDI and then they're in a packaged together also with the UDI. Does the label - do the labels of the individual devices have to refer to the UDI...

Woman: The (unintelligible)...

(Christina Savisaar): ...on the package. Is that what you're asking?

(Davia): Correct, like, the direct parts marked that goes on these two individual...

(Loretta Chi): Yes I...

(Davia): ...products.

(Loretta Chi): There's no way to link the individual devices to the package.

(Christina Savisaar): When there's an assorted package there's not an easy way to do that. You're not required to put on the label of the two separate devices the UDI of the package it may also come in. But when stakeholders are looking at your data and access GUDID it's useful, like, in the device description, to make that relationship clear to people.

Some people will put, you know, this is a package that contains DI-XYZ and DI and they list the device identifiers in the device description so that people can go to the individual device records for more information. Or some people in the reverse in their device description will say this is also sold with two other devices, you know, under this DI, just so it's clear when people are trying to find the record for your device and it's not because they have the label in front of them they're scanning.

They're trying to match up to their item master or something like that and they understand exactly what the record pertains to.

(Davia): So did you recommend that when we do the GUDID submission that we for the, like, the third part number I'll say where these two are bundled together that we would clarify that this is for two separate products?

(Loretta Chi): You would clarify that in device description.

Woman: Yes.

(Davia): Okay got it. So if that's the case if we clarified it in the device description we would not have to necessarily match the UDI of the package where it's bundled together to be the same UDI on these two individual (unintelligible).

(Loretta Chi): You wouldn't be able - not only would not - you wouldn't even be able to. I mean that would be impossible.

(Davia): Okay all right thank you.

Coordinator: Thank you next we have (Billy Zarconi), your line is open.

Man: Other kit components separately...

Man: And that was the pouch.

Man: (Unintelligible) the pouch.

Man: Never the pouch (unintelligible).

Coordinator: Mr. (Zarconi) your line is open.

Man: That's the correct - I believe that's a correct statement.

Man: So if I ask them a question say we have multiple items in our kit but we consider only one of those items to be a medical device. Is that considered a convenience kit.

Man: The answer is - their answer's going to be no.

Woman: Mr. (Zarcone).

Coordinator: Mr. (Zarcone)? Hi sir your line's open.

Man: Was that Mr. (Zarconi) you said?

Coordinator: Yes your line is open for question.

Man: So real a quick question, if we have what we believe is a kit and it only has one medical device in it but it has multiple items in it would that even be considered a convenience kit?

(Christina Savisaar): No. You have to have two or more different medical devices.

Man: Two or more different medical devices. Now do those two or more different medical devices have to be wrapped together in one package or just in the convenience kit?

(Loretta Chi): Well if it's in the convenience kit the convenience kit presumably would be a package of some sort.

Man: Oh okay got you. But still if only one of those items are a medical device then it's not considered a convenience kit.

(Loretta Chi): Correct.

Man: Even if they're packaged in 25 individual foil wrap medical devices in that kit.

(Loretta Chi): If they're - are they identical medical devices?

Man: Yes they're identical and there's foil wrapped in that kit.

(Loretta Chi): Okay then that's not a kit. That is a - is that a single-use device or a multiple use device?

Man: Single.

Man: Single use.

Man: It's a single use device.

(Christina Savisaar): It's not an implant?

Man: Correct.

(Loretta Chi): It's a single-use device and it's not an implant you might want...

Man: Correct.

Woman: (Unintelligible).

(Loretta Chi): Is that correct?

Man: Yes.

(Loretta Chi): Then you may be able to take a different exception. Not a convenience kit exception but an exception that's an 801.30(a)(3) which basically says (unintelligible)...

Man: 801.3083?

Woman: A-three.

(Loretta Chi): A as in Apple, three. So basically it's saying that if you have a single-use device that are packaged, several of them, that are packaged together, they're all the same version or model of a device and they're packaged together and they're intended to remain packaged together until used by the end user, then you only are required to have the UDI on the package and not on the individual devices.

Man: Okay that's excellent. So in...

Man: What's the definition there instead of a convenience kit?

(Loretta Chi): It is 801.30A as in Apple, 3. (Unintelligible).

Man: Right.

(Loretta Chi): And basically it's saying that if you have multiple single-use devices all of the same version or model that are packaged together and intended to remain packaged together until used by the end user and these are not implants then you are not required to have the UDI on the individual devices. You may have the UDI on the package itself.

Man: Which we do already right.

Man: Okay I have a question about that set of devices. This is a diagnostic device. One example, one version would be a pregnancy test. And the - each of those

pregnancy tests are single-use devices individually foil pouched and they go into a box of 25. And that box of 25 is sold under its own UDI.

In that box we also include what I'm going to call are control swabs. The control swab is used to ensure that the operator in the laboratory or physician's office can run a test and get a predetermined positive or negative pregnancy result.

(Loretta Chi): Yes I know what a control swab is.

Man: Yes.

(Loretta Chi): So your - so is that control swab a separate device?

Man: Well that's my question. In the context of it being a component of that kit is that medical - is that control swab considered a medical device on itself?

(Loretta Chi): Is it a separately approved or cleared by the FDA?

Man: No it's cleared as part of the product, the kit product.

(Loretta Chi): Well yes it - you know, first of all IVDs are outside of the scope of the convenience kit guidance.

Man: Right.

(Loretta Chi): I would suggest that you contact your - well it's no longer OIR because we've gotten reorged but I would contact what used to be your OIR reviewer to figure out whether that is considered a single device, whether the control and

the pregnancy kits themselves are considered together a device or whether they're considered separate devices.

Man: Okay.

Man: He's thinking.

Man: So because it's an in vitro diagnostic are we completely disconnected from the convenience kit requirement?

(Loretta Chi): Well when you say completely disconnected the guidance document does not - it does not apply to IVDs either way. Okay it's like the - just pretend the guidance documents for purposes of IVDs, the guidance document doesn't exist. So whatever...

Man: (Unintelligible).

(Loretta Chi): ...policy was in place, whatever the regulations were in place prior to the issuance of this guidance document it's still in effect.

Man: All right thank you very much.

Man: So but thank you for this webinar, it's been great.

Man: Okay.

Coordinator: Thank you and our last question comes from (Lacey Stuart), your line is open.

(Lacey Stuart): Yes so the question I have for you guys, we are a custom kit manufacturer that takes multiple finished medical devices and we package them and then they're sent off for ethylene oxide sterilization.

So we have two different types of packs, we have those packs that go through that process of sterilization and then we have packs where we package multiple sterile finished devices into a bundle kit that is then shipped to the customer that way.

So right now we have all of those that we do have listed with UDI but my first question for you is so one of the slides that you went over, talked about an exception for a sterile kit. So I was hoping you could clarify that just a little bit on the requirements for that sterilized kit.

(Loretta Chi): Well a kit - the reason why we talk about sterile is because if the kit is sterile and it isn't intended to be opened until the point of use...

(Lacey Stuart): Right.

(Loretta Chi): ...and then after that, you know, it's no longer sterile right. So it's been - all the contents have been compromised. And so at that point after the procedure's over everything gets disposed of. And that's the kind of the point we're trying to make there.

(Lacey Stuart): So we're saying that would be an exception then?

(Loretta Chi): That would be a convenience kit.

(Lacey Stuart): Yes.

(Loretta Chi): Right.

(Lacey Stuart): Okay so that does meet that which would require the UDI. And so the same for the non-sterile bundle that has all sterile individual components but the kit is supplied without going through ethylene oxide sterilization.

So now let's talk about those - the same types of kits, let's say, you know, that sterile convenience kit has ten widgets inside it and I decide to exchange one of those ten widgets for a different widget and internal tracking we show that as a revision. Would that require us to register a new UDI for that pack?

(Loretta Chi): Okay well I need to go back to your original question though because you said...

(Lacey Stuart): Okay.

(Loretta Chi): ...requires a UDI. They all require a UDI okay. The convenience kit exception is not whether the kit requires a UDI. All kits require a UDI. All devices require a UDI.

The exception is whether the - if it's qualified as under the exception whether the individual constituents within the kit require a UDI. So I need to make that part really clear.

(Lacey Stuart): Okay.

(Loretta Chi): Okay so that's what the - that's why we're saying that the sterile kit with all the constituents in there once it's opened, you know, they're compromised and the whole thing gets thrown out.

So okay now the question of what happens when you make a revision to a kit and whether that requires a new DI, well that goes back to whether you consider that a new version or model of the device.

(Lacey Stuart): So it's internally, you know, we number that item, you know, 12345 and then if we revise that kit we put a 001 at the end. So if we are internally on our labeling are showing the revision would that require us to register a new DI?

(Loretta Chi): You know, how you do your internal numbering system is not going to make the decision for us whether you do or do not require a new UDI. Your numbering system is your numbering system. It's whether you consider it a new version or model.

So if you consider adding a 0001 to the end of your catalog number or whatever constitutes a new UDI then - I mean a new version or model then it's a new version or model. I mean it's really up to the discretion of the labeler. It's not up to us.

(Lacey Stuart): Okay thank you.

Coordinator: Thank you and that was our last question.

Irene Aihie: Thank you this is Irene Aihie. We appreciate your participation and thoughtful questions. (Unintelligible) those presentation and transcript will be made available on the CDRH1 webpage at www.fda.gov/training/cdrh1 by Thursday, May 30.

If you have additional questions about today's presentation please use the contact information provided at the end of the slide presentation. As always we appreciate your feedback.

Following the conclusion of today's 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 all for participating in today's conference. You may disconnect your line and have a great day or a great evening.

END