

**NWX-HHS FDA**

**Moderator: Irene Aihie**  
**May 05, 2014**  
**2:30 pm CT**

Coordinator: Welcome and thank you for standing by. At this time all participants will be on listen-only mode until the question-and-answer session of today's call. At that time you can press star 1 to ask a question from the phone lines. I'd also like to inform parties that today's call is being recorded. If you have any objections you may disconnect at this time.

I'd now like to turn the call over to Miss Irene Aihie. Thank you, you may begin.

Irene Aihie: Hello and welcome to today's FDA CDRH 510(k) electronic submission pilot program presentation and live demonstration. I am Irene Aihie of CDRH Office of Communication and Education.

CDRH is conducting this pilot program to evaluate the new routes for submitting 510(k) applications that will guide the user through constructing, packaging, and submitting their 510(k) submission electronically without the need for submitting a hard copy.

Your presenters today will be two Center experts on eSubmission. Both from the Office of Device Evaluation, Biomedical Engineer Nelson Anderson and Patrick Axtell. We will begin the presentation outlining and describing the eSubmission program then follow up with a live demonstration of how to use the site and program.

Following the live demonstration we will open the lines for questions. This session will be recorded and posted to CDRH Learn.

Now I would like to turn it over to Nelson Anderson.

Nelson Anderson: Thank you, Irene. Good day to you, everyone. The Center for Devices and Radiological Health is conducting this pilot program to evaluate a system and process that enables creation, submission, and review of a 510(k) through an entirely electronic process. This is the next technological step beyond our eCopy program.

First of all, who is eligible to participate in the eSub pilot? If your device would fall under the reviewing purview of either the Cardiac Diagnostics Devices branch or the Peripheral Interventional Devices branch, both part of the Division of Cardiovascular Devices, and as a traditional unbundled 510(k) you are likely eligible to participate in the pilot.

Third party 510(k)s, special 510(k)s, and abbreviated 510(k)s are outside the scope of this pilot and will not be accepted.

Devices reviewed by the two branches are listed here. Please note that this is not an exhaustive list. If you have any questions as to whether your 510(k) submission may be eligible for the pilot program, please email us. The email

address and the information that should be included in that email will be provided later in this presentation.

The benefits of participating in this pilot program include downloadable software called eSubmitter that will assist you in creating a 510(k) submission much like tax preparation software guides you through the process of completing your taxes.

The 510(k) template in eSubmitter includes directions, advice, help text, links to relevant guidance documents regulations, and other resources. Our goal is to provide as much useful information during the 510(k) creation process as possible.

Since no mailing of a hard copy of the 510(k) submission is necessary, there will be a shorter transit time between applicants and the FDA. Also the cost of submitting a 510(k) will be reduced due to no longer having to print and ship a hard copy of the submission and no longer having to provide an eCopy on CD, DVD, or other media.

510(k)s that are accepted into the pilot program will not be subject to the Refuse to Accept decision. Since the eSubmitter 510(k) template requires the RTA elements be completed before it will package the submission, we are foregoing the official RTA decision. Any issues that would otherwise be related to an RTA decision will be included as part of the normal review process.

We hope to reduce the number of administrative type questions asked by the FDA during the pilot since many of the administrative aspects of the 510(k) submission such as organization, format, pagination, and completeness of basic submission information are handled by the eSubmitter template.

At a high level, the pilot process proceeds in this order. Use of the eSubmitter software to create the 510(k) submission, use of the FDA Electronic Submission Gateway, or ESG, to securely transmit the 510(k) to the FDA, and FDA review of the 510(k) after it has been logged in and processed.

All current MUDFA goals still apply to 510(k)s submitted in the eSubmission pilot. If you have additional information to submit during the review of a submission such as supplements or amendments you will make those changes or additions in the eSubmitter template and resend the package to the FDA.

Now for more detailed view of the pilot process. First the applicant uses eSubmitter to create their 510(k). eSubmitter outputs a Zip file containing the entire submission contents. The Zip file is then submitted through the Electronics Submission Gateway to the FDA.

Our 510(k) staff will check for an appropriate MUDFA fee payment and if present they will assign a 510(k) number to your submission. At this point a copy of the Zip file that you submitted will be loaded into our current document storage system. The electronic submission package will then be validated and processed.

Once the package has passed the validation checks and been processed, it will be loaded into the pilot storage system and the reviewers will then use a new custom interface to that we have developed to review the submission. If needed by the reviewer, the Zip file containing the submission in its original format will always be available in the current document storage system.

For those of you who are not familiar with our eSubmitter software, it is a free download from the FDA website. The URL download is provided on a later

slide. The software automatically updates itself with any changes made by the FDA every time it is run ensuring that you have the latest version of eSubmitter and the 510(k) template.

I've noted previously eSubmitter helps the applicant through the process of creating a 510(k) submission similar to how tax preparation software takes you through that process. The eSubmitter software is available for all who are interested including those who are not participating in the pilot.

We welcome and encourage you to download eSubmitter and provide feedback on the 510(k) template even if you are not a part of the pilot program. There is a one-pager available on our website regarding how they do this and the URL will be provided on a later slide.

The eSubmission pilot will utilize the current FDA Electronic Submissions Gateway. The ESG is already used for submissions of electronic medical device reporting in CDRH and also currently used by other Centers, CDER, CBER, CTP and CVM for various submission types.

If you would like to participate in the pilot and do not already have an ESG account you can apply for one. A link for more information on the ESG and ESG account application process is also provided on a later slide.

For those who do not have sufficient technological resources or time to create a new ESG account, we are providing an alternate option during the pilot program. MITRE has agreed to transmit 510(k) submission files on behalf of the applicant through their ESG account free of charge during the pilot and has a non-disclosure agreement available to ensure confidentiality of the contents of your submission.

For those of you who are not familiar with MITRE it is a non-for-profit organization that operates multiple federally funded research and development centers. They have no commercial interests, no owners, and no shareholders.

They have been very involved in the development of this pilot and have offered this service as a way to make pilot participation easier for those who do not already have the preexisting ESG account. For more information on this service provided by MITRE please contact to David Tanenbaum at the above email address.

This slide provides links for more information regarding the eSubmitter software and Electronic Submissions Gateway. The eSubmissions Pilot Program website contains additional information regarding this pilot as well as useful documents such as the pilot user guide and the eSubmitter 510(k) template valuation one-pager which I mentioned earlier for those who cannot participate in the pilot but who still wish to evaluate and provide feedback on the 510(k) template.

The Federal Register notice that was posted on the 30th of April can be found at the link above. If you have any questions or would like to be a part of the eSubmission pilot, please email us at [esubpilot@fda.hhs.gov](mailto:esubpilot@fda.hhs.gov). Please note that if you are interested in participating in the pilot, you need to contact us at this email address before submitting a 510(k).

When you email us, please include your company name, the trade or common name of your device, the primary proposed product code, and any predicate devices that may have been identified by this point.

We will respond with a confirmation message letting you know if your submission appears to be within the scope of this pilot or not. Or we'll ask for

additional information, most likely your indication for use, so that we can correctly make this determination.

Now I'd like to turn this presentation over to Patrick Axtell, who will demonstrate the eSubmitter software.

Patrick Axtell: Hello, my name is Patrick Axtell. I'm going to demo the template we've built within eSubmitter today.

When you first install and run the software from the links provided by Nels in his previous presentation and first run it for the first time, this is the first screen you'll see. This is the eSubmitter application. This application contains several templates which are used by different centers for many different types of electronic submissions.

This application has been used for years and so I don't plan on going through how to use eSubmitter application or anything about it, but if you have not used it before I'd direct you to the helpful tips tab here to provide some information about how to use it as well as the frequently asked questions tab which contains a link to the user manual.

Chapter 3 of that user manual I think you'll find it quite informative if you've never used this application before. When you first get started click on Create A New Submission. This allows you to see all the different templates used by all the different centers.

You can see we have some templates here from CBER, CDRH, CTP, and CVM. Our pilot is this one right here. Now we're calling it 510(k) Pre-Market Notifications and not eSubmissions because right now the only electronic transmission we have turned on within it is the 510(k).

It does actually contain one other, as well as another that is actually being built. Eventually we do want to include several other different types of electronic submissions within it and at that point we will change the name to eSubmission or something like that.

So in order to get started with it you just double click on it, just give it a default name whatever you want to choose. Typically the K number would be what you want to give it. And you can click Create. And this is the first page of the template we built. You can click on this Save icon to save it so you can get back to it from the start.

Now I'm not going to start from new. I have a test submission in here I want to start from. So I'm going to close this one. And I'm going to open an existing template. See this is the one I just saved right here but I'm going to start with this test submission right here.

And before I get started I want to briefly touch on a couple of questions I believe we'll expect - namely, what is the difference between this template and the Turbo 510(k)? In fact, you can see the Turbo 510(k) if I were to click on a new template. Turbo 510(k) is this template right here.

So one question is what is the difference between this template and Turbo 510(k)? Another question we may get is also what is the difference between this and RPS? So I want to briefly touch on these. Because I think that describing the differences between these two different types of application processes will more fully convey what we're trying to do, the purposes of this pilot.



So real quickly, first off, RPS stands for Regulated Product Submission. It is a globally harmonized submission package that is being evaluated by the FDA for use in submitting 510(k)s, and PMAs, and eventually many other submission types.

And it's a worldwide effort. Presently Anvisa from Brazil is contributing, PMDA from Japan, even China has now taken part, and apparently Russia is now trying to get in on the fun as well.

We have not committed to this yet. However if we do, the intention is that this RPS package would eventually go into a database which is the same database that this eSubmitter application is going to.

And this is a new electronic submission database that we're going to be testing in the pilot. In addition there is going to be a new viewing tool used by reviewers that will also be the other half of this pilot. So this new database and this viewing tool that would be used by the reviewers are the other half of the pilot that you (industry) are not going to actually be seeing.

In comparison to Turbo 510(k) there are five quick differences I would like to go over, the first one being our future plans for what we want to do with this. If you prefer software for example that - let's say that you prefer software that you would want to use in a web browser, or you want software that would work on a Mac, or a tablet, we want to know this information.

Presently eSubmitter cannot do these things. However if you would like to use eSubmitter, if you think eSubmitter is the way you would like to proceed with this perhaps because other centers use this software and you are used to it, you don't want to have to learn another application, or perhaps you just like the functions that are built into the eSubmitter.

The eSubmitter has some very good functions built in that pretty much it only can do since we built this internally. We'd like to hear that as well from you.

The second difference is the structure and the content of the submission package produced by eSubmitter is being electronically validated automatically when it is submitted.

You might ask why would we do this to something that we build internally? Why would we validate a package from software that we've internally built? And the reason being is because we want to eventually allow the industry to produce their own internal software if they choose.

And so if this were the case in the future when they submit that package to us, we'd need to validate that package to make sure it is what we expect and the structure and the content of that package that you send to us is what we are expecting.

And in order to do that we'd have to validate it according to something. And so what we built and what we're testing out with this is what's called an XSD, an XML Schema Definition. I'm not going to go into exactly what that is but basically it's something that we could send out to industry and they could use to build their own software and be able to submit their own packages to us.

The third difference is the fact that when I was building the software I was wanting it to be more of a walk through, more of a, not a form as many eSubmitter templates are, but something that someone could use to walk through the process of putting together a 510(k) application.

And in addition I wanted it to be more of a resource so that you can go to this application and, you know, look at the questions and get some information about the 510(k) process. And have it be a one-stop shop for these things.

And so as a result many guidances and different resources that reviewers use are built into it. So for example the software guidance, the standard ISO 10993-1, RTA guidance document the format for traditional and abbreviated 510(k)s. A lot of this information is built right in. And where things cannot be built in, we link to them.

The fourth big difference is the design. So just being designed by a reviewer the information that we're collecting is what a reviewer is expecting to see. And this is not something - for example, many of the templates are being produced by contractors. Contractors simply can't get a lot of the information that, and understand the nature of what a 510(k) is, to be able to collect the information that a reviewer is actually expecting.

And finally the process here is going to be completely electronic. As Nels showed there is no paper copy required for this. And so when you submit it the whole process is electronic except for one small step that still does require a human. And that step is the process by which we're getting the K number.

Other than that - and we're actually going to try to automate that process as well, perhaps even by the end of the pilot. And if we can get that process completely automated we're talking about minute after you submit this from the gateway to it being loaded into our tracking system in our database for review by the reviewers.

So with that I want to get started - I want to briefly go through this template and I'm going to focus in on a couple of questions that are built into the

template. The first thing I want to show you is the two buttons up here which are the Simple and the Expert tab

Basically what one does is if you choose the Simple then you can skip through the different screens like that. Or if you would like you can jump through it, just jump immediately from one to the other.

And when I mentioned nodes in this presentation each of these folders is a node. If I mention that, that's what I mean. In addition you have two tabs here. The reason why we're doing it like this is because in the preliminary information node pretty much every type of submission that we would receive requires some form of administrative documentation as well as some form of a device description and indications for use.

The second tab would be used for the specific information for that specific submission type. So in this pre-market notification has these very specific elements to it. Moving onto the first node, there is a question here we turned off at the very top. That question is what application you're submitting. In this case since we're only going to be accepting 510(k)s in this pilot we have disabled this question and had it not appear.

But usually you would have a question up here that says would you be submitting a 510(k), a 513(g), a pre-submission, what have you, and we would be providing information to you that would help the user determine which they would actually like to submit. Again that is presently turned off in the pilot.

And the first question you see here there are three icons. I want to go over these real quickly. One is the help texts. You click on the little light bulb and some help texts will come up. The majority of the questions within this

template have help texts associated with them to try to help the user walk through this process. The blue dot means that that response is required for you to successfully package the submission.

So at the end after you complete the submission, you need to make sure that all of the questions with the blue dot are answered. If they are not it won't allow you to package the submission. The packaging icon is right here.

And finally the red exclamation point - if you're in this view here, that red exclamation point - if you don't answer the question - it won't allow you to proceed to the next node if you don't answer that question. Obviously in Expert mode, I mean you can jump around and that exclamation point, it really is kind of useless.

And finally the checkmarks on the folders here. When you answer all the questions within a folder, you'll see a little check. If you haven't answered all the questions it'll be a question mark instead.

Moving down to the Administrative Information. You'll find for those who are familiar with the Form 3514 all of the information within this Administrative Information section here is from that form except for the cover letter. And this is an example of how we're building in different forms and such into the template. So you will not need to upload Form 3514 at any time.

Moving on to the Device Description. This node here is the most extensive and it's going to take me a little bit of time to go through it and show you a couple of the questions I want to make sure I focus in on because I think they are good examples of what we're trying to do in this template.

So first off going through you'll see there are several different questions, several different text fields and places where you can upload different attachments. And a lot of these questions come from the RTA guidance document. Some of these questions are meant to complement internal software used by our reviewers to review 510(k). Many questions are simply used to let the software know how to proceed.

So for example, this software question. If I were to go over here I could show you the software is turned on, it's black. This is an example of something that's turned off, it's grayed out. If I were to say the submission does not use software for example, it will know to turn that section off. Simple logic like that is built in.

Moving down, you'll notice this text box is asking you to insert a device description summary. You'll also notice down here we're asking for you to attach device description documentation. You might ask why, you know, what's going to keep me from simply typing "See the device description below and the attachment." It's not going to keep you from doing that.

And presently right now, right now you still need to submit - you still need to attach a 510(k) summary. However in the future we would like to produce that 510(k) summary for you. And presently in the pilot we will not be doing that.

However in the future the 510(k) summary that you need to attach into this template presently contains a device description summary. And that device description summary is required according to Regulation 807.92, Section A, Subsection 4.

And eventually when we are going to produce the 510(k) summary for you, you would need to type in a summary here because we would be using this

summary to produce in that section of the 510(k) summary so we can produce that for you.

Moving down you can see this is the part where you can indicate the components and accessories that you're using with your device. And this device regulation information question, I want to focus in on this one as well because this is a good example of where we're trying to make it more of a resource rather than a - as well as a walk-through system.

If you click on the help texts for this you'll see that it provides a lot of information about regulations, product codes, medical specialties, lots of different information that could be useful to the person trying to put together the submission.

And basically what the gist of this is that you're trying to figure out what the product code is for your device, the primary product code for your device. So you in putting this together can get information to determine how we, the FDA, are going to be regulating and how we're going to be reviewing your device.

So the first thing you would do is click this plus right here. And you're presented with two different options. One is the quick filter. So if you are familiar with the 510(k) process, familiar with the device you submitted before, you can quickly type in your product code and it'll pop up here for adding down below.

However if you're not that familiar with our submission structure and this is the first time you ever tried to put together a 510(k), you would use the help text I just showed you as well as this help text here which will let you know

how to use this question - particularly this mouse approach right here I want to bring your attention to.

And it'll help you walk through trying to determine what the proper product code is for your device to try to make it so you don't have to submit a 513(g), which is the submission type you would typically use to try to determine what that product code is.

And so let's say for example, you have a device that you've made and you never submitted a 510(k) before and it delivers current to the body with electrodes. And you found the certain precise stimulus parameters you could make it so when you put those electrodes on your body it'll reduce or eliminate pain in that area. And in your research you noted it's got a neurological method behind it. You're affecting the nerves in some way.

You're coming in here to try to figure out what exactly - how we're going to regulate this and how you should put your submission together. So you go down through the medical specialties using the help text I showed you before. You see that perhaps it will be in Neurology. So then you click on the regulation.

And you're presented with all the different types of devices that are within that medical specialty. And so running through here you can pretty much tell based on the name which ones would not apply, which ones would never be used.

And if you want to know more information you can right-click on it and choose this link and it'll open it up. And it'll provide you a description of that regulation if you wanted more information.



And so running through here, let's say you're jumping through and of course, it's got to be all the way at the end - you come upon this and you think this could be it. It could be the description provided that looks like the best fit for your device based on that description there. So you go with that regulation and double-click on it.

Now based on the help text again that I had previously showed - we're now down to just a couple of product codes. So running through those you know my device does not use magnets, my device does not break through the skin. Looking up this example, this would be the one you would choose. I've already added it down below so it's giving me an error.

This is an example of how someone could use this to kind of walk them through the process of trying to determine what their product code is. Now what would you do with the product code? So let me show you an example of that.

So you right-click on the product code, you have a product code link. And in doing - in clicking on that it'll tell you a lot of different information about things you need to know about your device.

So what branch is going to be reviewing it? What submission type is proper? So you can be sure a 510(k) is the proper submission type, the regulation number, the class. But also whether we have any standards that would be used that you should use in putting together your submission. Whether there are any guidance documents to help put the submission together and whether there are any accredited third parties which could help you with your submission as well.

In addition if you click on the help text, there's a link down here, click on it. You can type in the product code and it'll tell you all the different 510(k)s that have been approved lately - or cleared lately, sorry - cleared lately under that product code.

Moving on to indications for use. Note that we are not having you upload any indications for use form. You're simply going to type it in, and choose this information, and the software is producing the indications for use form for you. Now we move to the more specific information about the market implications.

Note that since the pilot is only for traditional 510(k)s we have disabled the question that will allow you to choose abbreviated or special. This is where you would find out more information about which you should actually choose.

Moving on. Finally when you get to the Substantial Equivalence Comparison, this is where you would add your predicate devices. So using information you got within that (pro code) question I just showed you, you could figure out which ones would be best to compare to your device and you could add those K numbers here.

We have some additional text fields here which again would be used for producing a 510(k) summary eventually. These three text fields here are required according to the RTA guidance documents. And finally the Substantial Equivalence Comparison which you would attach down here.

Moving on to the labeling. A lot of these questions are based on the RTA Guidance Documents, these here for example. Some are required according to regulation and either you would attach pictures of your device, packaging,

shipping, user manuals, be attached in this place here. And to attach, you just click on that plus button and choose the file on your computer.

Sterilization Information. So this is where you would list all the different components or the device if it's just a whole device, that you sterilize it. So you can click on detail to see this one that I added. There is different information required for devices that are sterilized. This information is required according to the RTA Guidance Document, as well as the Sterility Review Guidance K 90-1.

Shelf Life Node. These questions are also from the RTA Guidance Document. The logic from the RTA Guidance Document is also built into these. You are either required to answer this question here, these questions down here. You would simply upload any sterility key high-level disinfection information.

Patient Contact Component. Similar to the sterilization section, you would list all the patient contact components here. Click on detail to see the details of this one that I entered in. Note below here you can indicate the 510(k) number that - for this particular material your device may be similar to.

Or you can indicate whether the device - whether you are using the material differently in comparison to the predicate device. And if you are you can answer these two questions here and use this table provided at this link here to determine what tests you're going to need to provide.

Tests here. We have provided some information about some common tests we see down here as well. This is where you simply upload your biocompatibility testing if needed.

The Software Description Section. These questions would help you walk through the - to determine the level of concern of your device. So I need to answer these real quick since I've reset this section.

So I've answered no these questions and I answered yes to that question, but no to these, which determined I have a moderate level of concern. If I answered no to all of them, it determined I have a minor. Or if I answered yes to this one up here, it determined that I have a major level of concern.

And based on your level of concern, it would automatically determine which documentation you would need to provide right here. I'm going to go with minor for now. And since this got reset when I did that question before, I'm going to just type in some random information here. Forgive me for this.

I'm going to put in some random - this was already supposed to be filled out and got reset on me. And yes I'm just attaching random attachments right now. There's no choice, to move on with my example here. So I apologize for this.

Okay. Moving on to the EMC and EMT sections. Right here where you just - we're requesting you provide a summary and upload any documentation in regards to electromagnetic compatibility and the electrical, mechanical, or thermal safety.

Performance Testing. Depending on whether we say yes or no here, different sections will be able to turn on and off. I'm not going to go through this in any great detail. I'm going to try to get through this as quickly as I can.

Verification and Validation node here. Used for special 510(k)s and since those are beyond the scope of the pilot, presently just turned off. This would again just used for specials and we would accept feedback on that.

This node for reference, documentation providing journal articles here, which you would need. Finally moving on to administrative documentation. And note that we are requesting this documentation at the very end, as opposed to the beginning like we usually do and that was because we don't know what documentation you need here until we get to the end.

So for example, we don't know whether you need to provide clinical forms until you indicate whether you've provided clinical data. We don't know whether you need to upload any standards data report unless you indicated earlier that you are referencing standards and so on.

One part I want to bring your attention to is the Truthful and Accurate Statement. If you are the owner of the 510(k) and you will be signing this package that this produces, you can follow this help text here, you say yes. Then this software will produce your Truthful and Accurate Statement for you.

If however you are a consultant or someone other than the owner and you say no here, you will have to upload a Truthful and Accurate Statement that is signed by the owner of the 510(k).

Other Supportive Information. If for some reason there is information that you need to provide in your submission that was not obtained through any other nodes of this submission, or in this template, this is where you provide it.

And, finally, Submittal and Feedback. We provide some information about registration and listing, several links, and this is where you would upload your MUDFA cover sheet.

Package the submission once you're done. You click the package files icon here. Here is where you want it stored on your computer. Go to next. You list all the different attachments that you used in your submission. Finally, you sign it.

We have directions in or on the Web site as to how you would obtain this digital signature form, the .pfx. You attach and sign the submission, and this is where you read the Truthful and Accurate Statement and you will be signing it electronically.

And so what this is going to do is produce a Zip package on your computer that you would then submit to us via the ESG. So, if I go to my My Documents, this is the Zip file right here I would submit. So, I want to open this up real quick and show you what's inside. Presently I have a WinZip error on my side.

What you can see in here is you can see the folder of attachments, as well as the output files. So this is the PDF that the software is producing. The PDF version of what you just filled out. You can go through this to make sure everything is as you want. Truthful and Accurate Statement digitally signed. The IFU form produced for you.

To finish this up, I want to show you the process of amendments and supplements. So say you submitted your application and you didn't pay your user fee. Or let's say 10 days after you submitted, you suddenly realized, I forgot to submit that sterilization documentation. What you can do is you can submit an amendment. You can get the information that you need to submit an amendment from there.

So, when you indicate you have a supplement or amendment, you need to type in the 510(k) number that you received. Once we receive your 510(k), we send you the 510(k) number in an email and it would be that 510(k) number you would need to enter here in order to submit a supplement or an amendment for your submission.

So once you enter that in, you can go back through the application, the software section for example, and update one of your PDFs and reupload it. So, for example, then repackage it. I'm going to just quickly go through this because I want to show - and bear with me.

So now this is the amendment. And when you open it, you'll note that now we have a K number associated with the file that the forms and everything that's produced will automatically transfer that K number to all the different forms.

So let's say that now we've - the FDA has reviewed your submission and we have some additional information requests. And so we've provided these to you. You would go to the beginning here. You choose supplement.

So now you get the supplement tab. And in the supplement tab is where you would respond to each deficiency. So the idea here is you would copy and paste in the deficiency into this section here.

And, oh by the way, the eSubmitter application used to have this issue with copy and pasting from Word and PDFs where it wouldn't allow you to paste in special characters. That has now been fixed. And so you can copy and paste from any type of document now. So the idea is that you copy and paste in your deficiencies here so that we know what you are looking and you would type in your response here.

And any documentation that needed to be updated based on that deficiency, you would go back to the respective section, whether it be here or there, say it was shelf life. You would make the change to that this specific section. You would repackage the submission and you'd resend submission - that package, to us. And that concludes the demo.

Irene Aihie: Hello, operator? We'll now take questions from participants. We'd like to open the lines up for questions at this time.

Coordinator: If you would like to ask a question from the phone lines, please press star 1. You will be prompted to unmute your phone and record your name. Again it is star 1 to ask a question. One moment please for the first question.

The first question will be coming from (David Chadwick). Your line is now open.

(David Chadwick): Thank you. Gentlemen, I have two questions. One was am I going to be able to have headers on my pages and list confidential on my pages as I normally do today except for the summary? And my second question is, am I able to enter reference devices under my substantial equivalent area? Thank you.

Patrick Axtell: So to answer the second question first, you would be able to reference, put references, so - let me back up actually. The best way to answer the question would be to go back into the software.

So we have this related submission section, and this comes from Form 3514. You can list - you're supposed to list your predicated devices and any related prior submissions as well. Any sort of information submissions that you previously provided that related to your device. This is where you would list



those here. The Substantially Equivalent Section here, or here, you would only list the predicate devices here.

And the second question about the headers. For any documentation that you're uploading, so for example software comparison right here, that's just an attachment. So that would be a PDF or a Word document. You can attach any one of those things. Right here. So those can contain those headers.

(David Chadwick): But otherwise documents generated from this submission form don't have a header or does FDA automatically put a K number on it eventually, not automatically?

Patrick Axtell: Right. When we eventually get the K number, we would be putting the K number on those automatically.

(David Chadwick): Okay.

Patrick Axtell: As I showed there. Yes, we wouldn't be putting any headers or, you know, company header or anything like that.

(David Chadwick): Thank you.

Coordinator: The next question will be coming from (Claudia Jackson). Your line is now open.

(Claudia Jackson):Hi. This is (Claudia Jackson). I have a question about retention, in-house retention. Is there any way to export this file for our own company retention?

Patrick Axtell: Yes. So, the document that was produced that you would be submitting to us, you could just keep that document and that would be your file. That would be your submission package. So let me bring that back up again.

So, this package right here that's on your computer. You would - the idea is keep this. And this would be a copy of the submission package. And this PDF in this folder here would be sort of a representation of that package.

And note that it contains links to the different folders. Those links don't work right, right here, but it would work on your side. And you could again go directly to the attachments within that .zip) folder to see what those attachments are.

(Claudia Jackson): Okay, thanks.

Coordinator: I'm showing no further questions from the phone line.

Irene Aihie: Would you - can you remind all participants how to use their phone to ask questions?

Coordinator: If you would like to ask a question, it is star 1. You will press star 1 and be prompted to unmute and record your name.

The next question will be coming from (Claudia Jackson). Your line is now open.

(Claudia Jackson): Yes, I had another question. How long is the pilot supposed to run and what is the projected timeline for all submission types to become available for eSubmission?

Patrick Axtell: The pilot is intended to last through September although we may extend that a month because we were late in getting it started. The other submission types being added, the 513(g) is actually already added. It's simply been disabled. Pre-submission is being added. And other submission types after that, I don't know.

We don't have a plan for when those will be added yet. We're going to see how this pilot goes first to see - to have a plan adding these other submission types, for example PMA, IDE later on.

(Claudia Jackson): Okay, thank you.

Coordinator: The next question will be coming from (Deborah Manning). Your line is now open.

(Deborah Manning): Good afternoon. Early on there was reference to the information being shared with other countries in general. I guess the regulatory establishments within those organizations. How would proprietary information be omitted from that type of sharing if I indeed understood that correctly?

Patrick Axtell: I apologize. Perhaps I didn't explain that correctly. What I was describing earlier with RPS, that's a separate project. So that's a separate type of electronic submission process that's being worked on right now. FDA has not committed to that yet. And this - what I showed today is completely separate from that. It's kind of redundant with it to a point.

And I was bringing that up because it is another type of electronic submission process that I think a lot of people on the call today are aware of and are wondering about and so that's why I wanted to mention what the difference is between what we're doing here and RPS.

RPS would be intended to be used by larger companies, companies that can afford to build their own RPS software or buy that software from third-party vendors. Whereas this software we presented today is intended for the smaller Mom and Pops who need to be walked through the process and so on.

And, so, we would not be sharing this with any other regulatory authorities. The RPS package however that would be applied to other different regulatory authorities and that's beyond the scope of today.

(Claudia Jackson): And how is proprietary information handled with this?

Patrick Axtell: The same way it is now. So the only thing that's made public is what's made public now, which is the 510(k) summary and the IFU. All of the other information you provide here is being put into our data base. It is not being made public. It is kept private in the exact same way as it is now.

(Claudia Jackson): Thank you.

Coordinator: The next question is coming from (Lawrence Peterson). Your line is now open.

(Lawrence Peterson): Hi there. I missed the first half of this because I couldn't get on to the slideshow part, but I got on for the last half. But my question is, in order to participate in the pilot program, do you have to have a 510(k) that's completely ready to submit right now or do you develop it as you go along?

Patrick Axtell: No. So, what you can have - if you have a 510(k) that's already been constructed and you really want to be part of the pilot, you want to have that 510(k) be part of the pilot, what you can do is take the documentation from

that 510(k) package you have in-house right now and simply use this template and transfer the information from that folder into this template.

And that's how we tested this in-house before releasing it to industry is, you know, we made up our own packages and uploaded them, and transferred stuff into it. So we would be accepting applications through September.

So if you have - if you're in the process of putting it together right now and you want to use this template, you can do that right now. And if you take until September to get it together, that would be fine.

(Lawrence Peterson): Okay. Well, I have a 510(k), a traditional 510(k) that's 80% completed.

I've completed 80% of it and I already signed up for the pilot program and I was accepted. So, I guess I just take what I have and then enter the additional data into the template and then submit it?

Patrick Axtell: Correct. Yes, you just transfer everything into it, submit it via the ESG, and we would be - you're going to find that when you do submit the package via the Electronic Submission Gateway, that you're going to be receiving several acknowledgment emails, new ones that you don't right now receive.

So, right now you are receiving email that advises you that it was accepted, the user fee was properly paid, and that you get the K number and so on. You get one that's the RTA process was either - you were accepted or denied, for example.

You're going to be getting many more acknowledgment emails than that right now. And we would also be working directly with you in the process to make sure that there's no skip up in this electronic process.

(Lawrence Peterson): Okay. And on other question, a few of the sections contain forms which I'm very familiar with like Section 1 of a 510(k) is the medical device user fee cover sheet, which is Form 3601. And this is a form you normally can't just create. You have to make - they have to make sure you've made your payments and this and that.

And then it can only be produced online on the FDA Web site. So how am I going to complete this type of form?

Patrick Axtell: So you would complete it usually - this is one of the few forms that we need you to still upload. So where this is typically one of the very first forms we see in a submission, in this it's the one - well pretty much the last.

And so in this screen you see here, this is where you would upload the file. And within that, you would have that payment ID number. Eventually what we're going to be doing here is we're going to need you to - we're going to have a second question here which is going to be asking you to input that payment ID number.

And that would be necessary in order to completely automate the process of everything that occurs after you submit via the Gateway. So if we want to take out that one - there's one human presently that's standing between the Electronic Submission Gateway and the reviewer or the branch, I should say.

And if we're going to automate that process, we would need to be getting this payment ID number in a structured way outside of this form. So we would be collecting that from you eventually here separately. But for now, you submitting the - just uploading the user fee attachment would just be the way you do this.

(Lawrence Peterson): Great. Okay. Very good. Well thank you.

Patrick Axtell: Yes.

Coordinator: The next question is from (David Chadwick). Your line is now open.

(David Chadwick): Thank you. I had a question about size of files that can be uploaded. I've heard that 50MB limit has been taken away with using this eSubmitter. That's my first and one of my colleagues is asking if this eSubmission process will have any effect on FOI requests for our 510(k)s. Thank you.

Patrick Axtell: So the size limit for eSubmitter, I am not aware of a size limit. I am aware of one for the Gateway which is in the low gigabyte size. I think it's 2 gigabytes, but don't quote me on that. I'm not aware of the size limit for eSubmitter. So this can handle very, very large files.

(David Chadwick): eFiles at the moment are restricted to 50 Megs and you've got to split your large files into parts.

Patrick Axtell: Right. So the eCopy guidance and eCopy requirements, this - those are not being used here. So you do not have to abide by the eCopy guidance or any of the eCopy requirements for this submission process.

You don't also have to submit - or you don't also have to abide by the RTA guidance document either. There are many different guidance documents that you don't need to worry about in this process. And the second?

(David Chadwick): The second was...

Patrick Axtell: The FOI, right. There's nothing - there will be nothing changing in regards to the FOI. We're still going to be holding the submission in the same type of documentum that we were before. And any FOI requests could be obtained via the same methods as before.

(David Chadwick): Okay. Thank you.

Coordinator: The next question is from (Deborah Manning). Your line is now open.

(Deborah Manning): Hi. Sorry I didn't get them all in the first time. I'm just curious. If you have all the data - the gentleman that had 80%, if he had 100% of his data, about how long does it take to upload the information?

And you said we don't have to worry about the RTA checklist, but is the - like it had the prompts that said certain information is required. Is the RTA kind of built in so you can't submit it if you don't fill in that required information?

Patrick Axtell: Correct. So all the RTA guidance document questions are built in here. If for example you decide - so we cannot stop you from submitting - for example in your indications for use textbox, we can't stop you from submitting the recipe to pumpkin pie there if you really wanted to.

However that would obviously require, you know, cause an additional information request later on. So and that's how we would handle that in that point. So right now, we typically for most submissions coming in, we only have one additional information request.

If for some reason there's - you type in incorrect information here very badly, let's say, or you don't follow the directions that may result in two additional information requests. And that's how we would handle that.



The first question?

Man: If they have it 100% done.

Patrick Axtell: Oh right. If you have 100% done. So when we were doing our testing in-house and I had 100% done files and I was putting into this, it took me less - maybe 25 minutes to a half an hour to just transfer everything over, it depends on the complexity.

((Crosstalk))

Nelson Anderson: Yes it very much depends on the complexity of your 510(k). A simple one can be very quick, but, you know, a very large 510(k) obviously you have to put all the attachments in the correct spaces and whatnot. So it can take a little longer.

(Deborah Manning): Okay. Thank you.

Coordinator: I'm showing no further questions from the phone line.

Irene Aihie: This is Irene Aihie. Thank you for your participation today. Questions about the eSub pilot can be addressed to the address on your screen, which is [esubpilot@fda.hhs.gov](mailto:esubpilot@fda.hhs.gov).

If you have further questions outside of the scope of today's presentation, please email them to [cdhquestions@fda.hhs.gov](mailto:cdhquestions@fda.hhs.gov). For this and any other regulatory information, please visit our industry web resources at Device (Advice) and CDRH Learn.

As always we welcome your feedback. Thank you for participating and this concludes today's session.

Coordinator: That concludes today's conference. Thank you for participating. You may disconnect at this time.

END