

**FDA Webinar: De Novo Classification Process  
(Evaluation of Automatic Class III Designation)  
Moderator: Irene Aihie  
November 21, 2017  
1:00 pm ET**

Coordinator: Welcome and thank you for standing by. At this time, all lines will be on a listen only mode until the question and answer portion. At that time, if you'd like to ask a question, you may do so by pressing star then 1 and recording your first and last name. Today's call is being recorded. If you have any objections, you may disconnect at this time. I would now like to turn it over to your host for today, 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 October 30th, the FDA issued the final guidance for the De Novo Classification Process, Evaluation of Automatic Class III Designation. The purpose of the guidance is to provide updated recommendations for interacting with the FDA, including what information to submit when seeking a path to market via the De Novo classification process.

On this same date, the FDA also posted the draft items on Acceptance Review for De Novo Classification Requests. This draft item is not in effect at this time and is only open for comment purposes at this time. Today, Sergio de del Castillo, De Novo Program Lead in the Office of Device Evaluation here in CDRH, will present an overview of these two guidance documents. Following the presentation, we will open the line for your questions, related to the information provided during this presentation. Additionally, there are other (unintelligible) subject matter experts here with us today, to assist with the Q&A portion of our webinar. Now I give you Sergio.

Sergio de del Castillo: Thanks Irene. And thank you everyone for joining us today to talk about the De Novo classification process. So at the conclusion of today's presentation, you will be able to describe the exact purpose of a De Novo classification request; you will also be able to describe and identify the statutory changes that have occurred to the De Novo classification process, since its inception; you will be able to identify the purposes and the relevance of the two new guidance documents that we'll be discussing today; and finally, you will be able to identify other additional De Novo related resources at your disposal.

So here is an outline of today's presentation. I'll first start off by explaining what exactly is a De Novo request. Then we'll talk a little bit about the history of the De Novo Program and how it's changed over time. Then we'll get into the crux of today's webinar, which are the two new guidance documents, the first being the final De Novo Classification Process or Evaluation of Automatic Class III Designation. Then we'll talk about the draft guidance, Acceptance Review for De Novo Classification Requests. Again, this is a draft guidance. It is not in effect at this time and is only open for comment purposes. I'll then briefly explain some additional resources available to you. And at the conclusion of the presentation, we'll take any questions you might have.

So let's begin with what exactly is a De Novo classification request. So as I'm sure you're aware, it is a type of premarket submission where you are interested in receiving authorization from the agency to legally market your products. What makes De Novo unique is that it is specifically a request to the FDA to classify a new device into Class I or Class II using a risk based classification approach that's outlined in the Food, Drug & Cosmetics Act.

And it's specifically intended to request classification of devices that are by statute automatically classified into Class III, which is why De Novo is also known as an evaluation of automatic Class III designation. If a De Novo request is granted, not only are you able to legally market your product in the United States, we also create a new classification regulation for this new device type.

Over the years there have been many misconceptions about what a De Novo actually is. And I'd like to dispel some of those now.

A De Novo request is not a type of premarket notification or 510(k), and as such, there's no substantial equivalence or SE determination rendered in the De Novo itself. As I said, a De Novo is a classification request, not a SE determination. It's also not a type of PMA) or premarket application. And finally, a De Novo request is not a 513(g) request. A 513(g) request is asking the agency for a specific determination as to what is the class of a current product. But it is not itself a classification procedure.

Because De Novo is a classification process, as with any classification procedure, there are three goals that we're attempting to achieve. First, we're attempting to identify the probable risks to health, associated with the device when it is used as intended. Based on those risks identified, we then need to determine the level of control needed to mitigate those risks to health. If there is sufficient information to show that general controls alone can mitigate those risks, then we can place the device into Class I. If we determine that special controls are needed in addition to the general controls to mitigate those risks to health, then we would classify the device into Class 2II.

The final goal that we're attempting to achieve is to determine that the probable benefits of the device outweigh its probable risks to health. In

meeting these goals, this is how we attain reasonable assurance of safety and effectiveness for the products. You should be keeping these goals in mind throughout the presentation, as we'll be coming back to this, referring it to the other pieces of information that are discussed. Now I'm going to switch over to a brief history of the De Novo Program and its evolution over time.

On this slide you'll see a compressed timeline of the major statutory changes that have occurred since its inception in 1997. And I'm going to go through each one of these time points in more detail now. What we now know as the De Novo Program was actually created 20 years ago, through the passage of the FDA Modernization Act or FDAMA, in '97. This actually added a new part to Section 513 of the Food, Drug & Cosmetics Act, specifically Section 513(f)(2). Section 513 governs medical device classification.

This provided the opportunity for sponsors of medical devices to send in a request to the agency for evaluation of their automatic Class III designation and it granted the authority to the agency to classify certain devices into Class I or Class II, using the classification criteria under Section 513(a). At the time that the De Novo pathway was created, the FDA was required to render a final decision on their De Novo request within 60 FDA days. Also at the time the De Novo Program was created, there was only one mechanism by which you could submit your De Novo request.

First, you were required to submit a 510(k), to attempt to establish that your device was substantially equivalent to legally marketed devices. We then potentially could review that 510(k) and determine that your product is NSE, that is not substantially equivalent, to legally marketed devices. And we would potentially send you a high level NSE decision by a letter. When I say high level NSE, I mean the product doesn't have a predicate device available,

there is a new intended use or there are different technological characteristics that raise different questions of safety and effectiveness.

Once you've received this high level NSE decision letter, you are then within 30 days of the date of that letter, permitted to submit a De Novo classification request. This is a relatively short period of time between the date of the letter and when you can submit the De Novo. This is one of the reasons why for many years, we saw very few De Novo requests submitted to the agency for review. That changed significantly with the passage of the FDA Safety and Innovation Act or FDASIA, in July of 2012, also known as MDUFA III. The biggest change made through this legislation was that it removed the requirement to submit a 510(k) prior to submitting your De Novo request.

Effectively, this resulted now in two mechanisms by which you could submit your De Novo request. The original mechanism that I just described is called the post-NSE De Novo because it requires submission of a 510(k) and a high level NSE determination, before you can submit your De Novo. However, with FDASIA, we now have a new option available, what we call the direct De Novo. Using this option you can submit a direct - you can submit a De Novo request directly to the agency without any prior interaction.

Regardless of which option you choose for submitting your De Novo request, the review process for each is exactly the same, has no impact. Finally, the other change rendered by FDASIA, was that it increased the time in which the FDA had to render a final decision. It increased it from what was 60 FDA days to now 120 FDA days.

In December of 2016, the 21st Century Cures Act was signed into law. This also implemented two changes to the De Novo program that are significant. First, it removed the requirement for post NSE De Novo requests that the De

Novo be submitted within 30 days of the high level NSE determination. Now you may submit your De Novo request any time after receiving the NSE determination. The 21st Century Cures also clarified that some combination products may be able to be classified through the De Novo pathway. As you may know, combination products often raise complex, scientific and regulatory issues and questions. This also is true when we're considering combination products through classification of the - through the De Novo pathway. At this time, we're still developing our policy to determine in what circumstances combination products may be classified and how we would do so.

It is highly recommended that if you're interested in submitting a De Novo request for a combination product that you seek early interaction and feedback with the agency, through our pre-submission program. This would be helpful in verifying that your product is in fact eligible for De Novo classification and if so, what data and evidence would be needed to support a future De Novo request.

Finally, I'll touch upon the recently passed FDA Reauthorization Act of 2017 or FDARA, also known as MDUFA IV. Specifically, it granted the agency authority to collect user fees for the first time for De Novo classification requests.

I'll also be talking about the performance goals and the submission checklist or RTA guidance that are formal commitments within the MDUFA IV commitment letter that was developed with the FDA and representatives from the medical device industry. So as I said, for the first time we are now collecting user fees for De Novo classification requests. By law, the standard De Novo user fee is set to 30% of the PMA) standard user fee. For those who receive small business qualification, you are entitled to a reduction of that

standard fee, equal to 25% of the De Novo standard user fee. For the first year of MDUFA IV in fiscal year 2018, the standard user fee is \$93,229 and if you receive a small business qualification, you are eligible for a reduced fee, which is equal to \$23,307.

For the first time also, De Novo requests will be subject to performance goals. The performance goal will be based on rendering a final decision, that is to grant or decline, within 150 FDA days. This is different than the statutory deadline of 120 FDA days. That is not a mistake. That is deliberate. And a performance goal in each year, MDUFA IV, are based on the percentage of the De Novo request received in that fiscal year, reaching a final decision. In the first year of MDUFA IV, fiscal year 2018, the performance goal is 50%. By the end of MDUFA IV in fiscal year 2022, that percentage rises to 70%.

On this slide we are illustrating the total number of De Novo requests that have been received in CDRH over time, beginning in fiscal year 2011, through the end of fiscal year 2017. This slide greatly illustrates the impact that some of these statutory changes have had on the De Novo Program over time. In particular, with the passage of FDASIA in 2012, we saw a large increase in the number of De Novo requests being submitted to the agency, from that point forward and we've seen a steady increase over time.

With the passage of FDARA and the implantation of user fees and performance goals that were to be started in fiscal year 2018, we saw yet another large increase in the number of De Novo requests coming to the agency. What this slide also illustrates is that there's still a considerable amount of interest in the De Novo classification process and it also shows that this is a viable alternative pathway to market for novel and innovative products. For this reason, we recognize the great need for greater transparency in the De Novo review process, to insure that there's an efficient

and timely review, as well as to communicate very clearly, what are the current statutory requirements.

This is a great segue into the crux of today's webinar, which is the two new guidance documents that we'll be discussing in more detail. The first again, is a final guidance document entitled De Novo Classification Process (Evaluation of Automatic Class III Designation). As a shorthand, we'll be referring to this document as the De Novo Program Guidance. Later we'll be talking about the draft guidance document entitled Acceptance Review for De Novo Classification Requests. As a shorthand, we will refer to this document as the draft De Novo refuse to accept, or RTA, guidance. Again, I want to point out that this last draft guidance is not in effect at this time, and it's for comment purposes only.

So let's first begin with the final De Novo Program Guidance. The purpose of this document is to provide an overview of the De Novo classification pathway and FDA's review process of that premarket submission. As I just stated a few minutes ago, the guidance summarizes the legal foundation for De Novo classification and the significant statutory changes that have occurred over time and that impacted the De Novo Program.

In the remaining slides I'm going to explain what else the guidance does. It explains when De Novo classification is and is not appropriate; that is, a discussion of the concept of eligibility for De Novo. We'll also be talking about the importance of early interaction with the agency, through our Pre-Submission program, to obtain feedback on future De Novo requests. We'll also discuss the recommended content for inclusion in a De Novo request. And finally, I'll discuss what happens when a De Novo request is granted by the agency.



Let's first talk about the classification summary otherwise known as the eligibility section. This is one of the most key pieces that you should be worried about when you're considering whether or not your product is appropriate for De Novo classification. First, it must meet the definition of a medical device under Section 201(h) of the Food, Drug & Cosmetics Act. There cannot be a predicate device. That is if you attempted to demonstrate substantial equivalence, you would be again, found NSE, either for new intended use or for different technological characteristics that raised different questions of safety and effectiveness.

You also cannot fit into any existing classification regulation, Class I, II or III. That is if there is a regulation that describes your device type and it has already been classified you may not come in through the De Novo Program. Finally, if we have an approved PMA or PMAs, for that same device type, you are also not eligible for De Novo classification. If we determine that your product is not eligible for De Novo classification, we intend to decline the De Novo request and no substantive review of the information will be done.

As I mentioned earlier, earlier interaction with the agency can be beneficial to both you and the agency, when determining whether or not something is in fact appropriate for De Novo classification. And we can do that through our Pre-Submission process. If in fact we determine that the product is appropriate for De Novo classification, it would also be a great opportunity to identify the valid scientific evidence that would be needed to support your future De Novo request.

Finally, this is also an excellent opportunity to establish an initial working relationship with those FDA staff who will likely be reviewing your De Novo request when it is submitted.

For the first time, we now have something in the public domain that explains what our expectations are for content of a De Novo request. An attachment to the guidance provides a high level summary of that recommended content. It identifies the key sections of a De Novo request that should be included and what information and data should be included into those sections.

We also clarify the attachment that, where applicable, you may incorporate information by reference. For example, if you did submit a 510(k) prior to your De Novo request and there was any testing information included in it, you could incorporate that information by reference to the previous 510(k) and section number and page number.

I'm now going to go through the specific sections that are included in the recommended content attachment. The first series of bullets are information that we would generally include with any premarket submission.

First is administrative information - who are you; who are the official contacts for the file and all of their appropriate contact information. We'd also like a summary of any significant regulatory history that is relevant to the subject device. For example, if you have any prior submissions for the FDA for the same device, whether that be a previous 510(k) or a pre-submission, it would be helpful to identify those submissions in the De Novo request itself and explain, if feedback was provided, how the feedback was addressed specifically in your De Novo request.

Again, this information here on this slide is information that we would typically see for any premarket submission. We either want to have a summary of the device description, its principles of operation and its major components; we'd also want to understand what are the proposed indications for use and intended use; and in particular, if there's been any changes made

to the device based on any prior submission of that device, we'd want to know what those changes are and how they impact the information that has been included in the De Novo request.

Again, one of the key pieces for De Novo is determining that the product is in fact eligible for De Novo classification. We highly recommend that you conduct a search of legally marketed devices and classification regulations of potentially the same type, which will generate a list of potentially similar classification regulations, cleared 510(k)s, approved PMAs and/or product codes. For each of those items that you include in that list, we would recommend that you explain why the subject device is different or doesn't fit within anything you've identified.

For example, you may determine that your subject device, in comparison to a cleared 510(k), has a new intended use or different technological characteristics that raise different questions of safety and effectiveness. Or you may determine that there are different risks to health associated with the subject device, in comparison to that prior 510(k) clearance, in which case that might require additional data or different controls, to mitigate them.

Since this is a classification procedure, it's recommended that you include the recommended classification for your device, whether that be Class II or Class III. If you recommend Class III, then you must propose the special controls that would be appropriate for mitigating the risks to health that you've identified. You should provide any supporting protocols and/or data or evidence that would be needed to support any aspect of your De Novo request, particularly any of the mitigation measures. And then we want a summary of the benefits provided by your device and the identified probable risks to health. This last point speaks directly to two of the classification goals that I mentioned earlier in the presentation.

Another key piece that's highly recommended for inclusion in your De Novo is a summary of the risk and mitigation information. We recommend that this be provided in a tabular format and would summarize all of the identified probable risks to health; the measures that would be needed to mitigate each risk to health; and where within the De Novo you have your supporting data and information for each of the proposed mitigation measures.

On this slide we have a reproduction of the sample table that's included in the De Novo Program Guidance. As I said, this will summarize all of the identified probable risks to health in the left hand column, all of the recommended mitigation measures for each identified risk in the middle column. And then in the last column, you would explain where within the De Novo the supporting information is available. In this example, one commonly identified risk to health is adverse tissue reaction. A commonly cited mitigation measure is biocompatibility testing or evaluation, which could be a special control. And then we would recommend, if that's the case, that you include the specific section and page number, where biocompatibility testing and evaluation is located.

This information is extremely helpful to us when we conduct our review of the De Novo request, as it forms the foundation for the actual classification process.

Finally, speaking to the third goal of classification, we need to determine that there's a positive benefit risk assessment for the product. This assessment will be conducted in accordance with the recommendations set forth in the guidance entitled *Factors to Consider When Making Benefit Risk Determinations in Medical Device Premarket Approval and De Novo Classifications*. It is highly recommended that you also refer to this guidance

document when you're developing the content for your benefit risk consideration section.

Finally, we would also recommend that you include a copy of the device labeling. This information will be important to us to verify the proposed indications for use and intended use. And if you're proposing special controls that are related to the labeling, we will verify that your device labeling is in conformance with those proposed special controls.

Finally, I want to talk about what happens when we actually grant the De Novo request. If we grant the De Novo, we will send a granting order or letter to you and at that point you may now legally market your device in the US. Also, upon the issuance of that granting order, that device that has been granted through De Novo can serve as a predicate device for future 510(k) submissions. Also, the granting order establishes the new classification regulation that we created for that device type and if Class II it will show a risk/mitigation table similar to what we've asked you to include as part of your De Novo request and if applicable, the special controls that apply to that device type.

We will post to our Web site the granting order that is sent to the company and we will also post a decision summary, which we also call our Transparency Summary on our Web site. Finally, by law, we are required to publish a Notice in the Federal Register, announcing the new classification regulation and, if Class II, special controls. It is through this mechanism that the Code of Federal Regulations is updated with the new classification regulation. That ends the portion of the De Novo Program Guidance.

We're now going to switch over to the draft De Novo RTA guidance. Again, this guidance is draft, it is not final, it is not in effect at this time, and it is open for comment purposes only.

The purpose of this guidance, if finalized, would be to ensure that the De Novo request meets a minimum threshold of administrative completeness in order for us to conduct a substantive review. The idea is that by doing so, it would help to facilitate a more efficient and timely review once we actually begin the substantive review process. If you have any prior experience with 510(k)s or PMAs, you'll see that the RTA policy and format is very similar to that which already exists for 510(k) and PMA. And finally, I did want to point out that one of our MDUFA IV commitments was to develop a draft and final RTA guidance document, also referred to as a submission checklist guidance, in the MDUFA IV commitment letter.

Again, if finalized, the idea here is that the guidance would ensure that the De Novo's administratively complete with all of the information that would be needed to start our substantive review. But the RTA review process itself, is not a substantive review. That is we're simply looking to see that certain pieces of information exist in the file. If finalized, our intent would be to complete the RTA review of the De Novo within 15 calendar days of receiving the De Novo request. If that De Novo RTA review is not completed within 15 calendar days, then if finalized, we would consider that De Novo to be accepted. Finally, if the guidance is published in final, we may have up to a 60 day transition period in order to operationalize all of the recommendations in those guidance documents.

One key difference between this guidance document and the RTA guidance documents that exist for 510(k) and PMA is that there's actually two separate checklists currently included.

In Appendix A we have the acceptance checklist. These are content elements that are required to be included in your De Novo request. I'm not going to go through all of them today, but some examples of required elements would include the intended use, device description and if you're recommending Class II, the proposed special controls for that device. We also have another checklist in Appendix B of the guidance, entitled the Recommended Content Checklist. And as that name suggests, these are content elements that are not required to be included in a De Novo request, however we highly recommend that they do be included.

In many cases, the content elements that we've identified in Appendix B are those things that are typically identified as deficiencies during our review process. Therefore, by adhering to some of the recommended content elements in those checklists, you may help to mitigate or minimize the number of questions that you receive during the substantive review. Some examples of recommended content elements include identification of any prior submissions for the same device; the classification summary or eligibility analysis for your product; and a copy of the device labeling.

Again, this is a draft guidance document. It is not in effect at this time and it's open for comment purposes only. We would greatly appreciate your reading the guidance and providing any comments or suggestions electronically, through Regulations.gov, using the docket number that's listed here on this slide. The comment period is currently open and will close on December 29, 2017, in just about a month or so. That concludes the portion regarding the two guidance documents. I now want to briefly talk about some additional resources that are available to you if you're interested in the De Novo classification process.

On this slide I just have listed here the two guidance documents that we just discussed and hyperlinks to both of those. Here I also have a link to the benefit risk guidance that applies to De Novo classification requests. Again, we highly recommend that you look at this when developing the benefit risk content portion of your De Novo request. Because we have user fees in effect for the first time for De Novo, we also developed a user fees and refunds guidance for De Novos, which is available at this link here. Also, because we have performance goals in place for the first time, we also issued a new guidance on the various actions that the FDA and industry can take on a De Novo request, and its impact on the review clock and performance goals.

And then finally, as I mentioned earlier, there is a commitment letter that was developed between the agency and representatives for the medical device industry for MDUFA IV. This outlines all of our commitments to the MDUFA IV period, including those that are specific to the De Novo process. Finally, there are two last pieces that I'd like to highlight. You may be familiar with CDRH's Device Advice Web site. This includes a lot of information about medical devices generally, both premarket and post market. And there is a dedicated page for De Novo requests. We recently updated this page to conform to the information that's included in the De Novo Program Guidance, as well as some additional information that might be beneficial to you. Finally, in this last bullet, this is a link to our publicly accessible De Novo classification request database. This is a database for all De Novo requests that have been granted in CDRH and includes information about those specific products, including the granting order and transparency summary.

And that concludes our presentation. We will begin taking questions shortly. I would also like to remind you that in the room today we have Scott McFarland. He is the Associate Director Regulatory Counsel in our Office of In Vitro Diagnostics and Radiological Health, also known as OIR. If you



have any in vitro diagnostic specific questions, he may be able to help you in that regard.

Coordinator: At this time if you'd like to ask a question, you may do so by pressing star then 1 and recording your first and last name. To withdraw your question, you may press star then 2. Again, to ask a question, please press star then 1, unmute your phone and record your first and last name. One moment for the first question please.

Sergio de del Castillo: Thank you very much. While we're waiting for the questions to come in, I did want to highlight one issue that is commonly asked by the Center, and that talks about what happens if we receive more than one De Novo request for the same device type at the same time. This is actually outlined in the final De Novo Program Guidance, so you may reference it there as well. Essentially, if we had more than one De Novo request for the same device type, we will review both and at such time as one of the De Novo requests is ready to be granted, we will inform the other company that they are now no longer eligible for De Novo because we granted another De Novo request and there's now an available predicate device.

We will let you know that you are able to either withdraw your De Novo request and submit a 510(k) using the recently granted De Novo device as a predicate, or we will continue with the review and we will likely decline your De Novo due to being ineligible for De Novo classification.

Coordinator: We do have a question. It comes from (Sue Farina). Your line is open.

(Sue Farina): Hi. Thank you. My question regards the extent to which changes from a predicate or predicate devices and the indications for use, impact the decision to grant or deny a request for De Novo classification.

Sergio de del Castillo: That's a great question. So this goes back to the issue of eligibility and determining what we have previously cleared or approved as a legally marketed device. So if you already have 510(k) clearance for a product and you're making changes to the indications for use, it is possible that some of those changes may result in a new intended use, in which case again, it would be found NSE. And by that point you may be able to submit a De Novo request for classification.

In that instance, what we would be saying essentially is because there is a new intended use, it is a different device type, in which case it would be eligible for De Novo classification.

(Sue Farina): Thank you.

Coordinator: Our next question comes from (Jennifer Dodelyn). Your line is open.

(Jennifer Dodelyn): Hi. Thank you. This question actually builds on the last question. If a device went through the De Novo process and was classified, now there's another similar device but with a different intended use coming through, but the special controls that came out as part of the De Novo process indicated that all new devices require clinical data to support the intended use. Is there any advantage to using the De Novo process for new intended use, as opposed to just sending in a 510(k) with clinical data?

Sergio de del Castillo: So let me clarify. In this instance you're talking about a product that has been - that's legally marketed through the granting of a De Novo request. We've created a new calcification regulation; devices of the same type must submit a 510(k). You're saying that this new device, however, has a new intended use. If that's the case, then it sounds like we would find that device

not substantially equivalent to the De Novo device, in which case you would either have to come in with a De Novo request or submit a PMA. So the question regarding the clinical data special control wouldn't apply in this case, because you are not able to come in as a 510(k).

(Jennifer Dodelyn): Okay. Thank you.

Coordinator: Again, if you'd like to ask a question, please press star then 1 and record your first and last name. Our next question comes from (David Weiner). Your line is open.

(David Weiner): Thank you. Once a De Novo request has been granted, what is the term that's used to signify that; the equivalent term to something that's FDA cleared if a 510(k) has been granted?

Sergio de del Castillo: That's a great question and also a very common one. This is actually discussed in the final De Novo program guidance too. Essentially when we have rendered a positive decision on the De Novo request we say it has been granted. The guidance points out that this is similar to the concept of a cleared 510(k) or an approved PMA. But the most important thing to remember here is that if something is granted through De Novo, it is legally marketed at that point. You now have authorization to market the product legally in the United States.

(David Weiner): Thank you.

Sergio de del Castillo: You're welcome.

Coordinator: Our next question comes from (Quinn Hong). Your line is open.

(Quinn Hong): Yes, thank you. Thank you for the great summary, Sergio. I do have a question regarding - this is stepping back for a sponsor. Let's say that the sponsor looks at its device and determines that the device meets the eligibility criteria for a De Novo as you provided on one of your earlier slides, but then decides that it would rather submit a PMA. So is that a choice by the sponsor or could - or is that something that the FDA would react on? Could you please comment on that?

Sergio de del Castillo: Certainly. Another great question and a very common one. So I would point out that by statute, if something is determined to be automatically Class III, technically the company would have to either submit a PMA or they may come in with a De Novo classification request. However, it's not required to come in with one or the other. That is, it is up to the company to decide which one they would like to submit to the agency. As for how one goes about making that choice, that's going to be highly dependent upon the specifics of the company, the device and what the long term and short term business strategies are for that company.

(Quinn Hong): Thank you.

Sergio de del Castillo: Sure.

Coordinator: Our next question comes from (Harvey Harditt). Your line is open.

(Harvey Harditt): Under what circumstances is the De Novo request eligible for a user fee refund?

Sergio de del Castillo: Great question. So I referenced in the resources section a new guidance on De Novo user fees. I would recommend that you look at that. It does spell out the situation where a refund may be appropriate. And really there are very

few. Essentially, if you mistakenly provide a user fee for something that doesn't require one, then we - you would be eligible to request a refund. Otherwise, there really are no other situations where you could request a refund.

(Harvey Harditt): What if...

Sergio de del Castillo: I'm sorry. There's one last thing. I take that back. There's one other situation where you can request a refund. If you have submitted your De Novo request, you've paid your user fee, but you have not submitted a valid eCopy and so you're put on eCopy hold. If you choose not to submit a future valid eCopy, you can instead say I just prefer to request a refund and just have that deleted from the system. Those are the only two situations in which you could request a refund.

(Harvey Harditt): Okay. Thank you.

Sergio de del Castillo: Sure.

Coordinator: Again, if you'd like to ask a question, please press star then 1 and record your first and last name. Our next question comes from (Alison Kamayama). Your line is open.

(Alison Kamayama): Hi Sergio. Great talk. And I don't know if this was answered just now as I was recording my name and I couldn't hear what was said, but for the example that you gave that if two De Novos are submitted at the same time, one is granted and the other one is close to being granted and that one would be sort of booted out and sent via the 510(k) pathway, are they looking at a brand new user fee for that then? So essentially, \$93,000 submission kicked out or denied and then they are looking at another \$10,500 510(k)?

Sergio de del Castillo: So in a situation where again, we have more than one De Novo request submitted at roughly the same time, one of those De Novos is granted and so the submitter of the other De Novo now has to come in with a 510(k). Yes, they would be subject to the user fees for 510(k)s, as would everyone else.

(Alison Kamayama): Awesome. Thanks.

Sergio de del Castillo: Sure.

Coordinator: I'm showing no additional questions. I would like to hand the call back to Irene Aihie.

Irene Aihie: Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questions. Today's presentation and transcript will be made available on the CDRH Learn Web page at [www.FDA.gov/Training/CDRHLearn](http://www.FDA.gov/Training/CDRHLearn), by Friday, December 1st. 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. This survey can be found at [www.FDA.gov/CDRHWebinar](http://www.FDA.gov/CDRHWebinar), immediately following the conclusion of today's live webinar. Again, thank you for participating and this concludes today's webinar.

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