Welcome and thank you for standing by. At this time all participants will be in a listen-only mode until the question and answer session of today’s call.

At the time you may press Star 1 to ask a question from the phone lines.

I’d like to inform all 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 Ms. Irene Aihie. Thank you. You may begin.

Thank you. Hello and welcome to today’s FDA Webinar to discuss the recently published final guidance document titled 510(k) Program Evaluating Substantial Equivalence and Premarket Notification.

I am Irene Aihie of CDRHs Office of Communication and Education. And I’ll be your moderator for today’s discussion.
On July 28 FDA published the final guidance document which clarifies the current regulatory framework policies and practices of the 510(k) premarket review process.

Today Marjorie Shulman, the Director of the Premarket Notification Program and CDRHs Office of Device Evaluation will present an overview of the guidance document.

Following Marjorie’s presentation we will open the call for questions. At that time Marjorie and several other regulatory experts from CDRH will be available to provide clarification and answer questions.

Today’s slide presentation, audio recording and written transcript will be available on the CDRH Learn section of the FDA Web site. Now I’d like to turn it over to Marjorie.

Marjorie Shulman: Thank you. Welcome. My name is Marjorie Schulman. And I want to thank you for taking your time today to listen to this presentation. We hope you find it helpful and informative.

First I’ll start with a little background, K86-3 Blue Book memorandum the guidance on the CDRH Premarket Notification Review Program also known as 510(k) issued on June 30, 1986.

It was a general discussion regarding the process of determining substantial equivalence between a new device and a predicate device if issued prior to FDA implementation of good guidance practices.
The new 510(k) paradigm or alternate approaches to demonstrate substantial equivalence and premarket notifications guidance document issued March 20, 1998.

It introduced the special and abbreviated 510(k) program. And it explains the differences between traditional, special and abbreviated 510(k)s with respect to the scope and submission content.

Neither document has been updated since initial publication.

So for the background, the draft guidance document evaluating substantial equivalence in premarket notification 510(k) issued December 28, 2011.

It is a grand undertaking by a number of dedicated FDA employees who put in a lot of time, effort and thought into this document.

It’s intended to offer greater clarity on topics discussed in K86-3 and the new 510(k) paradigm guidance document.

We received over 400 comments. Most of the comments were on the special 510(k) technological characteristics and predicate device sections.

FDA carefully reviewed all the comments and modified the draft guidance document to address those.

We do believe we reviewed all the comments and took each one into consideration and as a result we did as I just said modified the document.

So the draft guidance document was revised to give a clearer - to clearly - clearer explanation and the intended value of the primary predicate concept
which I’ll explain a bit later, include more examples to illustrate FDA’s decision making process which we hope you will find very helpful and include an appendix with a sample 510(k) summary to demonstrate the level of detail expected in each session - section which I’ll also go into more detail later.

In response to the comments there was industry concern relating to the inclusion of the special 510(k) program section given the connection to deciding when to submit a new 510(k) for device modification.

So we heard you. And in response the special and abbreviated sections were removed. FDA intends to finalize these sections separately and the new 510(k) paradigm guidance remains in effect.

So now we’ll move on to the discussion of the final guidance. We are announcing the availability of the guidance titled the 510(k) Program Evaluating Substantial Equivalence in Premarket Notification 510(k).

It describes FDA’s current review practices for 510(k) submissions by describing the regulatory framework, policies and underlying practices.

It does replace K86-3 guidance. And it was issued in accordance with FDA’s GGP regulation 21CFR10.115.

The guidance highlights is there is a flowchart modification, discussion of new terms, illustrated examples for different not substantially equivalent categories and a 510(k) summary and - context content explanation. I know what I’m saying.

We’ll get into further detail on these subjects in the following slides.
For the flowchart modification it’s been previously unmodified since its introduction in K86-3. And it was updated to incorporate statutory terminology. And the language mirrors section 513I of the Federal Food Drug and Cosmetic Act and 21CFR807.100.

It is cosmetically reorganized for increased clarity and visually streamlined. It is available in Appendix A of the guidance document and is not intended to be used as a standalone document. The most important message about this flowchart is the decision points did not change.

We’ve introduced the new terms primary predicate and reference device. Primary predicate is the device they identified predicate with indications and technology most similar to the device subject to the subject device when multiple predicates are identified. And this can facilitate a timely review and well supported decisions.

A reference device is a legally marketed device intended to provide scientific information to support safety and effectiveness.

Reference device is not a predicate and cannot be used to support decision points one through four on the flowchart.

There are illustrative examples of each in the guidance document. And there’s a glossary of significant terminology in Appendix D.

Other terms that may not sound familiar are one multiple predicates which is where two or more predicate devices that have been provided to support an SE decision.
If using multiple predicate devices to demonstrate substantial equivalence each predicate device must have the same intended use as the new device and any different technological characteristics between the new device and the predicate must not raise different questions of safety and effectiveness.

Multiple predicates can also include devices such as a multi-perimeter monitor and a device construct. Examples are available in the guidance document.

And everyone’s favorite term split predicate which is using one legally marketed device for intended use and a different legally marketed device for technological characteristics to demonstrate substantial equivalent. The use of split predicates is inconsistent with the 510(k) regulatory standard.

As we try to clarify this in the guidance you do not need a primary predicate - you do need a primary predicate to get you through all the way through the flowchart. This is not a change from how we have made decisions in the past.

So the illustrative examples, the NSC categories are unchanged and fully explained. We have lack of predicate, new intended use, different questions of safety and effectiveness and inadequate performance data.

The first three remove the device from the 510(k) pathway. The fourth inadequate performance data allows the device to be remitted as a 510(k) with the adequate data.

We also have multiple examples of each NSE type described in this guidance. And finally in one guidance document we have discussed both intended use and indication fees.
The 510(k) summary is part of this guidance document. And the guidance includes additional discussion and examples on 510(k) summery requirements and context.

Appendix B is a discussion on the 510(k) summary document requirements. And it provides clarification to facilitate compliance with 510(k) summary content requirements which can be found under 21CFR807.82. Each subpart of the regulation is explained with suggested contact - content.

Appendix C is a sample of the compliant 510(k) summary. And that’s intended to provide an example of the format and the content expected.

The information required in the summary follows 21CFR807.92. We believe by following these requirements the summaries will be more helpful to companies by showing what information was required for the predicate and will increase transparency.

A file will not be refused during the refused to accept process for missing information in the summary. This will be a substantive review item. But the summary should contain all of the elements outlined in the regulation.

One of my favorite sayings by George Bernard Shaw is the single biggest problem in communication is the illusion that it is taking place. We hope you find this guidance helpful and it’s clarifying the 510(k) program for you.

We want to continue the communication so comments on this final guidance may be submitted at any time to the following Web site and electronic comments www.regulations.gov.
We will now take any questions on this guidance, or comments or accolades. Thank you for participating. You can send your questions to the Division of Industry and Consumer Education at dice@fda.hhs.gov.

And for more information on the regulation of medical devices please visit CDRH Learn and Device Advice in the medical device section of fda.gov.

Thank you.

Coordinator: Thank you. If you would like to ask a question from the phone lines please press Star 1. You will be prompted to un-mute your phone and record your name. Again it’s Star 1 to ask a question. And one moment please for the first question.

And there are no questions in queue at this time.

Irene Aihie: I think we should just give it a few more minutes. Can you just double check to make sure all of the callers understand how to prompt for question?

Coordinator: Absolutely. Again to ask a question from the phone lines please press Star 1. Okay and one moment, we do have a question in queue.

And our first question comes from Sam Mirza. Sir your line is open.

Sam Mirza: Hi. This is Sam Mirza from Philips Healthcare. Ms. Shulman I think you alluded to it’s in your presentation that special and abbreviated 510(k)s are excluded from this guidance, is that correct?

Marjorie Shulman: Yes that is correct. But they still are in a fact under the new 510(k) paradigm. We...
Sam Mirza: I got it.

Marjorie Shulman: ...in the draft that came out it was included all in the draft that we addressed specials and abbreviated but now it’s been - we removed it from this guidance document and the other one is still in effect. So we - that has not changed at all. We are still accepting them.

Sam Mirza: Very good. Thank you.

Marjorie Shulman: You’re welcome.

Irene Aihie: Okay. We can take the next caller please.

Coordinator: Thank you. And our next question comes from Greg Levine. Sir your line is open.

Greg Levine: Yes hi thank you. This is Greg Levine with Ropes & Gray. Thank you for the presentation and the guidance. I have a question about the use of the primary predicate by FDA.

And I was wondering if you could explain a little more about the purpose of that and the function it will serve from FDA’s perspective?

And, you know, particularly I’m thinking because the FDA has said it will accept multiple predicates particularly if you have a device that’s combining features from other previously cleared devices, you know, what - so if I have let’s say device that’s combining features from two previously cleared devices what is the purpose of identifying a predicate because it seems like in some instances that could be frankly somewhat - something of then arbitrary
determination which ones predicate versus which one is primary versus non-primary?

Marjorie Shulman: Thank you. That’s an excellent question. The purpose of the primary predicate is the device with the indications and for use and the technological characteristics that are most similar to the new device. So it should be identified within the 510(k) submission.

The multiple it predicates are certainly allowed also but you need one primary predicate to get you all the way through the flowchart.

Sometimes two things could be equal and you are just picking one to be the primary predicate. You can also would for a multi-perimeter monitor you could have the primary predicate be that monitor so it’s really a combination of a lot of devices. I’m sorry what was the other part of the question was...

Greg Levine: Well I mean, you know, I guess that answers the piece of the question that addresses whether you, you know, the decision frankly could be, you know, flip a coin in some cases.

I guess what I’m really trying to understand is when, you know, why is FDA requiring a primary, you know, what is the role of that and, you know, how does that frankly matter?

Marjorie Shulman: So that’s not new to the program. We’ve always required a primary predicate. And it’s really to determine the substantial equivalent. So you need a legally marketed predicate device.
And the legally marketed predicate advice can be one that’s been 510(k)’d, it could be one that was pre-amendment device, it could be one that’s been reclassified or a de novo’d device.

So that’s your primary predicate. But then you may change the indication or the technology. And that’s where you might bring in other examples. But you have one primary predicate that has the overall intended use of the device that you’re looking to market.

Greg Levine: Thank you.

Coordinator: Thank you. And our next question comes from (Patricia Lehman). Your line is open.

(Patricia Lehman): Hi. Thank you. This is (Patricia Lehman) from (EmeaCorp). And I was just wondering if you could tell me if the agency anticipates that there will be any changes on the application forms that might reflect any kind of new term in the new guidance?

Marjorie Shulman: I’m sorry the changes on the application form?

(Patricia Lehman): Yes.

Marjorie Shulman: Of the cover sheet, are you talking about the cover sheet for...

(Patricia Lehman): Yes, any of the forms yes.

Marjorie Shulman: Yes. We are looking to update any forms that do need to be updated for these changes. And then we’re just looking to update that anyway to make
some just cosmetic changes that were needed anyway but we will announce
those when they do, out.

In the meantime you’re welcome to use the forms that are out there. They’re
still valid for logging in any 510(k) or any application.

And the information that we pull off them is the same for the trade name, and
the company name and the email address, et cetera.

(Patricia Lehman): Okay thank you.

Marjorie Shulman: Thank you.

Coordinator: Thank you. And our next question comes from (JD). Sir your line is open.

(JD): Yes. Thank you very much. My name is (unintelligible) calling you from
Annidis Corporation in Ottawa.

Sorry my question is not exactly on the guidance but on the mechanism to
provide the information to FDA.

Is the electronic method is the only method to be used to communicate with
the FDA for a submission of a 510(k)?

Marjorie Shulman: Yes. That’s a good question. We do require an electronic copy of your
510(k) at this point an electronic copy and a hard copy.

We don’t accept just a hard copy. So we do have an electronic submission
guidance document that’s available on the Web...
Marjorie Shulman: ...that can walk you through that on how to submit that.

So any information submitted to us even as a supplement or anything that comes through the document center should include an electronic copy.

(JD): Okay. Thank you very much.

Marjorie Shulman: Thank you.

Coordinator: Thank you. And our next question comes from James Fedorka. Sir your line is open.

James Fedorka: Yes hi James Fedorka, from Sylvan Fiberoptics. We’re - we have a product that was 510(k) back in 1991. It’s been around for a while. And we’re looking to - we’re exploring another product would be we feel is a substantial equivalent to the product we have. But I guess if you could please explain to me what a split predicate is please?

Marjorie Shulman: So a split predicate is what we do not accept and we haven’t accepted in the past. Maybe I’m sure someone out there probably can come up with an example where we have.

But a split predicate is where you’re taking one legally marketed predicate device...

James Fedorka: Okay.
Marjorie Shulman: ...and it doesn’t get all the way through the flowchart. It might be not substantially equivalent for a new intended use.

And at that point you’re bringing in another predicate to get it further down the flowchart in technology.

So really it’s kind of like a - it really doesn’t have a full predicate that can get you all the way through the flowchart.

It’s almost an imaginary device at this point because we don’t have a legally marketed predicate device for it.

James Fedorka: Oh okay. Well so our product then is already 510(k) then the new product which will be manufactured will be actually private labeled for us.

It’s five it - a 510(k) but as a - I’m not sure if it’s going to meet exactly the wording so to speak in our 510(k) that we originally filed.

Marjorie Shulman: That’s okay. That’s the beauty of the 510(k) process you don’t have to be exactly like your predicate you can have a new indication for use or a new technology.

James Fedorka: Okay great.

Marjorie Shulman: Great.

James Fedorka: Well very good. Well thank you very much, very informative. Appreciate it. Thank you.

Marjorie Shulman: Thank you.
Coordinator: Thank you. And our next question comes from Bob Hoy. Your line is open.

Bob Hoy: Hi. Bob Hoy from Surgical Frontiers here. Thank you for the presentation. I had a question about the reference device example 1 in the guidance.

And as I read it through it seemed like the actual subject device and the predicate device the subject device would have made it all the way through the flowchart without the reference device.

And my question is, what is the purpose of the reference device if the rationale or the performance data is enough to tell us that the difference in technological characteristics raises no new issues of safety or effectiveness why would a reference device be included?

Marjorie Shulman: So we’re not saying you need a reference device per se. We’re saying if you have a reference device that may help the review then it’s certainly helpful to add that.

If you can get all the way through the flowchart with just the predicate device a reference device is not needed.

If there’s some information that we may gain from the reference device that maybe it’s a material that’s been used before so we know what kind of testing or questions are asked or the material of the device itself or anything like that that’s going to be helpful in the review.

But it’s not a requirement to have the reference device it’s just any other information you may know about the - your device that you think would be helpful in showing substantial equivalence.
Bob Hoy: Okay so even though it has different indication for use the technology has been cleared and it’s helpful to understand how it was cleared?

Marjorie Shulman: Right. So that’s helpful for us and probably helpful for you too if you look at the other companies 510(k) summary and especially one of these new ones that will appear on the Web soon that will show you what testing was required for that technology.

And - because as previously before and now new indications go through 510(k) all the time so does different technology as long as it doesn’t raise different questions of safety and effectiveness.

Bob Hoy: Okay great. Thank you.

Marjorie Shulman: Thank you.

Coordinator: Thank you. And our next question comes from (Molly). Ma’am your line is open.

(Molly): My question has been answered. Thanks.

Coordinator: Thank you. And our next question comes from (Ivan Spango). Your line is open.

(Ivan Spango): Thank you. I am participating only via the audio. I and I don’t have access to - I didn’t have access to the slides so this may have been more obvious in the slides.
But if we’re developing technology that appears to have substantial equivalence to legally marketed devices but it’s a new application in a new part of the body would that then require additional demonstration of efficacy and safety for that particular new use?

Marjorie Shulman: I would say yes. So we’re going to look at the indication of where on the body it’s being used and then that’s probably going to need some kind of data.

I would probably suggest that you submit a pre-submission to the division to make sure that everyone’s on the same page before you go off and do any studies for the data. So that’s a tool available for you too but that’s probably going to need data.

(Ivan Spango): Okay all right.

Marjorie Shulman: I’d say yes.

(Ivan Spango): Okay. Thank you.

Marjorie Shulman: Thank you.

Coordinator: Thank you. In our next question comes from (Lorraine Calzetta). Your line is open.

(Lorraine Calzetta): Yes hi. Good afternoon. My question is regarding the actual designation of the primary predicate.

Is FDA now requiring us to actually state in the submission this is the primary predicate or is it just inferred as you go down the checklist that this is the primary?
And - because I think another gentleman might have stated that sometimes there’s a gray area because you actually have two that could both be primary predicates and you’re trying to combine and give a lot of information regarding the fact that you have a couple of predicates that could fit the bill.

So - and then in terms of a reference device do they want you to actually state this is a reference device or you’re just using the backup information in there?

Marjorie Shulman: We would -- that’s a great question and we should have made that clearer - - we would love for you to clearly label what is the predicate device and what are the reference devices.

That’s going to help us kind of build like a predicate tree on what was substantial equivalent to what and go back in time that way and then the reference devices we know. If all things being equal and there’s two primary predicates well then really you just get to pick one.

(Lorraine Calzetta): Okay great. Thank you very much.

Marjorie Shulman: And just in addition if there are two you would pick the one with the higher class and the one most like the device you’re claiming equivalence too but if all those things are equal then you would just pick one.

(Lorraine Calzetta): Okay fantastic. Thank you for your assistance.

Marjorie Shulman: Thank you.

Coordinator: Thank you. And our next question comes from (Steve Ziemba). Serve your line is open.
(Steve Ziemba): Thanks very much. Ms. Shulman my name is (Steve Ziemba). Hey I’m a little bit confused on the difference between splitting predicates or splitting infinities perhaps is a better way to look at that and multiple predicates.

In other words I believe what you said was a split predicate device or at least one device has a different intended use whereas multiple predicates would have the same intended use except I heard you say several times that you could use the 510(k) process to expand or add new uses or are indications which I would presume would have needed some data from either a some sort of a safety and effectiveness study or from another predicate.

So if I can’t bring it in as a split predicate and I can’t bring it in as a multiple predicates how do I bring it in?

Marjorie Shulman: So no that’s a good clarification. And you’re right that that the difference in indication for use in technology probably would require some kind of data.

What we’re saying for a split predicate is that you don’t have one predicate device that can get you all the way through the flowchart.

And that was not allowed previously in the 510(k) program. And we just clarified it for this guidance document.

So what you’re talking about if you’re using a reference device or another predicate you can bring that in as long as you have one primary predicate that gets you all the way through the flowchart.

(Steve Ziemba): So to use the example...
Marjorie Shulman: Is that...

(Steve Ziemba): Well to use the example in the guidance document, you know, you’ve got a knee implant whatever it was in there that, you know, is cleared with, you know, material A and whatever the indicated use is.

And say I want to bring in another knee implant it’s, you know, made from a different material and maybe it’s for a slightly different population like maybe an older or a younger population is that appropriate to use as a multiple predicate?

Marjorie Shulman: That’s a multiple predicate. No I’m sorry that’s a reference device I’m sorry.

(Steve Ziemba): Okay. So...

Marjorie Shulman: Hold on one second.

Dr. Joni Foy: Right this is Dr. Joni Foy from the Office of Device Evaluation.

(Steve Ziemba): Yes ma’am.

Dr. Joni Foy: So just to clarify the example that you’re talking about is actually a reference device. We don’t consider a reference device a predicate.

When you are utilizing multiple predicates it is two or more devices that you can walk all the way through the flowchart.
And so the distinction that we’re trying to make with identification of a primary predicate is to pick the one predicate that you think is most similar to your product.

It’s not a requirement that you have to only identify one but it helps to streamline the review process because we look and your characterization in comparison is done to that particular product.

So that’s the impetus for a primary predicate is to try to streamline both the testing that you do on your end as well as the review process on the agency side.

(Steve Ziemba): Thank you.

Woman: Thank you Dr. Foy.

Coordinator: Thank you. And our next question comes from Craig Coombs. Sir your line is open.

Craig Coombs: Hi. This is Craig Coombs, Coombs Medical Devices Consulting. Ms. Shulman we’re still trying to sort through this issue of when different technological characteristics raise new questions of stating effectiveness and you provided several examples and I’d like to focus in on that first one that you did of showing the different technologies have the same intended use as far as serving as biological indicators. Now that’s on Page 21.

Our, you know, I just when I look at that specific example I don’t see that they do raise new questions of safety and efficacy.
I mean the main questions of safety and efficacy for any diagnostic like that are sensitivity, specificity, false positive false negative. They’re the same for both assays.

Now certainly they do raise different testing methodologies because they have different technology different testing methodologies to show that they meet the same criteria.

I just what we’re not understanding particularly because I don’t want this to be chilling on innovation how is the need for different ways of testing the methodology interpreted as new safety and effectiveness questions?

Marjorie Shulman: So we look at that because these questions were not asked with the predicate device. And that’s what we consider a different question of technology.

So that would be a question that wasn’t asked with the predicate device and that’s why it would be different.

Again that’s not new to the decision making process those are ones that we would have found not substantially equivalent before the issuance of the guidance document.

I can understand what you’re saying that it - you may not read it the same way but that’s what we believe that it is a different question of technology because it was not asked in the predicate.

Craig Coombs: Thank you.

Marjorie Shulman: Thank you
Coordinator: Thank you. And our next question comes from (Robin Statzinger). Your line is open.

(Robin Statzinger): Hi. This is (Robin Statzinger) calling in from (Acculab). Thank you for your presentation.

In a follow-up to the last question and I think it kind of leads into my question so I think one of the things that we’re a little concerned about are - if we use a predicate that has a 510(k) from maybe five to ten years ago or even further back a lot of times the information in a 510(k) summary is pretty vague. It doesn’t have as much detail as what FDA is now requesting in this guidance.

So we may not know whether the agency had evaluated certain aspects of safety and effectiveness in that review.

So I guess then my question would be does FDA expect to receive a lot more de novo requests and some of these de novo requests may come after an NSE letter.

So it seems like in the guidance there’s a lot of examples of when you would get NSE. And based on maybe some of things I’m hearing now it sounds like there may be a lot more NSE letters that are going to be given out to industry and therefore perhaps more de novo requests?

Marjorie Shulman: Yes. Thank you for your comment. We do not expect the NSE rate to increase. We do not expect to issue more NSE determinations.
If you had a question on what information was required for maybe the predicate device you could always submit (Qsub) and discuss it with the division.

But we’re looking for the change in your technology from the predicate that would be a different question of safety and effectiveness.

So that you don’t necessarily have to know from the summary what was asked in the other - in the predicate 510(k).

You can also request the file through Freedom of Information if you’re interested in that. And that’s why we’re hoping that these summaries that the part of the reg that’s been in the regulation since the inception of the summary and the statement is going to help with questions exactly like this.

(Robin Statzinger): Thank you. One just one other follow-up question, does FDA feel that this guidance will have any effect on bundled 510(k)s?

Marjorie Shulman: No we do not feel it should change anything about bundling the 510(k)s. If you could bundle before you can bundle now.

(Robin Statzinger): Okay. Thank you.

Marjorie Shulman: Thank you.

Coordinator: Thank you. And our next question comes from Elaine Lee. Your line is open.

Elaine Lee: Thank you. Thanks for the Webinar and the chance to ask questions. This is Elaine Lee from Intuitive Surgical.
And my question is also on reference devices. I was a little confused by one of your slides that said a reference device cannot be used for a decision point on the flowchart but in the guidance it talks about using the reference device for supporting scientific methodology at decision point 5A.

So I was wondering if you could just clarify what the distinction was regarding what you’re trying to say about not being used as a decision point?

Marjorie Shulman: So basically that kind of ties into the split predicate. You can’t use a reference device to bring in another predicate to get you past that decision point if you don’t have a legally marketed device that can get you all the way through the flowchart....

Elaine Lee: Okay.

Marjorie Shulman: ...for the first four points, so the first four points on the flowchart.

So that’s why - but it certainly is going to be helpful to the reviewer and for you to include that so we know what kind of information you’re looking for.

So that’s all we meant by that for the reference device that it shouldn’t be to get you further down the flowchart but it certainly has a part in the review.

Elaine Lee: So you mean that it - you can’t use your reference device to get you through the first four decision points, is that which your...

Marjorie Shulman: Correct.

Elaine Lee: ...(unintelligible)?
Marjorie Shulman: Correct.

Elaine Lee: Okay thank you.

Marjorie Shulman: Yes the intended use, the predicate the legally marketed predicate device, intended use new technology.

Coordinator: Thank you. And our next question comes from Claude Berthoin. Sir your line is open.

Claude Berthoin: Yes good afternoon Mrs. Shulman. This is Claude Berthoin. I’m with John Gillespie of the Enterprise International FDA consultant. We’ve talked to before. Thank you for your presentation, and nice to talk to you again.

I take the opportunity today to ask you if you have any plan to open a new category down the road of 510(k) in the future?

For a lack of a better name I’m calling I’m labeling this category of me to product. And let me define what I’m thinking about.

This is when the same device has already cleared multiple times by independent OEM of the same manufacturer.

Obviously the situation is the manufacturer did not file a 510(k). And then, you know, that part component is actually a full device. And each distributor is filing a 510(k).

So the FDA already has the information, already has all the tests, safety and effectiveness has been demonstrated.
We’re wondering why - how we could shortcut in a way a device that’s already been approved and in the knowledge of the FDA?

As an example there is a manufacturer of a dental sensor in France, then is imported in the US, and there is a companies that have filed the exact same sensor under different names, et cetera. And we’re about to do a ninth one and we’re kind of like frustrated.

We think this should be simplified and certainly equivalency has been demonstrated.

Marjorie Shulman:  So thank you for your question and I do understand what you’re saying. And you’re right. If the person had filed a 510(k) then the private label distributors would be exempt under the 510(k) program and that’s in the regulations.

We don’t...

Claude Berthoin:  Exactly.

Marjorie Shulman:  ....have any - right. We don’t have any plans of making another type of 510(k). Has anyone talked to the manufacture and suggested that they submit a 510(k)?

Claude Berthoin:  We have actually. They don’t want to consider themselves a medical device manufacturer. And that’s kind of an odd situation because of the physical characteristic of the device, you know, they are an electronic wafer company but actually the device they produce is the exact device.
The software is simply the additional components but there are already three companies using the same software.

So that’s kind of an odd situation. We wish we could have access or have the reviewers would have access to the information and could say yes you’re right it’s the same thing, you know, let’s take a shortcut.

We have a ruling here or a specific category that allows me to products if I can call them that way. And we understand there are legal issues of bringing other people’s file but on the other hand this was simply via the work at FDA.

The - the distributor is always willing to pay the fee. And, you know, if the product is the same and, you know, we think that there should be something about this issue.

Marjorie Shulman: Right. I understand what you’re saying. And we may have to discuss this later off line. There is something I can discuss with you later about a master file. Maybe that company would like to submit a master file. And there’s no charge for that and put that proprietary information in the master file than the other ones could reference it. They’re still going to have to submit a 510(k) but I think we may want to discuss this later off line.

Claude Berthoin: Thank you so very much. I look forward to do that. Thank you.

Marjorie Shulman: You’re welcome.

Coordinator: Thank you. And the next question comes from (Cheryl Wagner). Ma’am your line is open.
(Cheryl Wagner): Hello. This is (Cheryl Wagner). Thank you for the presentation today. I just had a quick question.

You had mentioned about that there will be additional (unintelligible) special and abbreviated do you have an estimated timeline for when that may happen?

Marjorie Shulman: That’s a great question and no I don’t, so not this year. I think that’s a safe bet.

(Cheryl Wagner): I would say not, this late in the year for that already. Okay thank you.

Marjorie Shulman: Yes. Thanks. Sorry. Sorry I don’t have a better answer.

Coordinator: Thank you. And the next question comes from (Kelly Kaharchek). Your line is open.

(Kelly Kaharchek): Hello. Thank you for the opportunity to ask a question. My name is (Kelly Kaharchek). And I work with Stryker. My question is in regard to combinations devices.

So I noticed here that the guidance is signed off by CDRH and CBER. And I guess my question is more when you have a combination product you’re taking two regulated components that have say they have the same intended use but when you add them together you’re inherently altering the technology or characteristics.

Is this kind of indicating that without being able to use split predicate most combination products would have to be - would have to go down the path of either de novo or a DMA?
Marjorie Shulman: So that may be a bit specific for this because we do have plenty of 510(k) devices that may have a drug component or a biological component. It doesn’t necessarily mean it would be not substantially equivalent.

We may have to go to the office of combination products to see who - which center would take the lead on it.

(Kelly Kaharchek): Okay but...

Marjorie Shulman: Go ahead.

(Kelly Kaharchek): So would you be able to reference both if both of the, you know, the drug and the device were legally marketed before (unintelligible) you would be able to talk to both of those or would you have to pick one of those as a primary predicate?

Marjorie Shulman: You would need to pick one as a primary predicate. And then if you’re adding the drug or the biologic but we may have to discuss this if you have something specific in mind as opposed to just a general question we’ll probably want to discuss that with you before you go down the path of submitting any kind of application to make sure it’s not an NME or anything like that.

(Kelly Kaharchek): All right. Thank you.

Marjorie Shulman: Yes New Molecular Entity.

Coordinator: Thank you. And our next question comes from (Abby Macutti). Ma’am your line is open.
(Abby Macutti): Hi. My question is around in predicate and reference devices. So for submissions that go in now is it an FDA expectation that every submission if there are multiple devices purely identify primary and reference devices?

And if you didn’t get - did get a submission for the - in the next month or so where a primary predicate was not identified clearly would you refuse to accept?

Marjorie Shulman: So no we would not refuse to accept it. And anything that’s currently under review we’re not going to contact the companies and go back and ask for which was the primary predicate and which were the reference devices.

It’s just for any ones in the future and if you have one that you’ve already prepared and it’s ready to be sent here we don’t expect to redo it at this time either. So it’s not going to be a refuse to accept item.

(Abby Macutti): Thank you so much.

Marjorie Shulman: Thank you.

Coordinator: Thank you. And our next question comes from (Harold Tilky). Sir your line is open.

(Harold Tilky): Yes this is (Harold Tilky) with Starkey Hearing Technologies. Thank you for the seminar and the chance to ask questions.

And I was looking at your table. And I was wondering if you advocate using that table as well for determining whether you need to send in a 510(k) for a modified device or if you can have - use that to help you determine if a letter to file is sufficient?
Marjorie Shulman: So no. This is not the guidance document that you would make that decision you would go to the when went to submit a 510(k) for a change or a modification.

That document is still in effect. And that’s the one that you would reference to make that decision on whether or not it’s a sufficient change that would require a new 510(k).

(Harold Tilky): Okay all right. Understand I just needed some clarification. Thank you.

Marjorie Shulman: Yes, no thank you.

Coordinator: Thank you. Enter next question comes from Raj. Sir your line is open.

Raj Kasbekar: Yes hi this is Raj Kasbekar, Kaz USA. I think you actually already answered my question. My question was same similar to the one posed before as to when this is affective and if we are submitting in the next few weeks would you expect this new terminology?

Marjorie Shulman: Right. So for the reference device and all that the summary of course we would expect to follow the regulation but it will not be a refuse to accept item.

Coordinator: Thank you. And our next question comes from (Marcia Zucker). Ma’am your line is open.

(Marcia Zucker): Good afternoon. Thank you. We do a lot of work with point of care devices. And so we’re working with whole blood devices and usually we have a point of care predicate and a laboratory analyzer as a reference analyzer.
Now since the point of care predicate would get us through points one through four in the flowchart would it be then reasonable to assume that when doing the accuracy studies, the method comparison study studies be done to the reference is more for - which is generally assumed to be closer to truth then another point of care device?

Marjorie Shulman: That is an excellent question which I do not have an answer for you right off the bat. I can tell you a couple things that you can do right now. There will be an IVD roundtable scheduled for Tuesday, November 18, 2014.

But in the meantime we can have you contact our division of IVD devices. And they could help you with that specific question.

I don’t have the response rate here but we would - we will get you the response as soon as possible. So you can send it - the question to the DICE address at fda@hhs.gov and we will certainly get you a response. I’m sorry I don’t have a response for you now.

(Marcia Zucker): Okay. Thank you very much I will just send a note to the DICE email.

Marjorie Shulman: Thank you.

Coordinator: Thank you. And our next question comes from (John Beasley). Sir your line is open.

(John Beasley): Thank you very much. My question relates to understanding all these definitions when you put them together.
So for example we note it at you have definitions for intended use. You have definitions for indications for use and then you have these new definitions for primary predicate and multiple predicates.

So when submitting a 510(k) for a change in the clinical context, or the clinical setting, or the setting food changing for example from clinical use to home use all right is it a correct assessment that you cannot use your own device as a primary predicate because your original device is cleared for the clinical use because there’s a difference in indications for use and intended use?

Marjorie Shulman: No. You can use your own device as the primary predicate and you know the most about your device. The only reason maybe we’d want to use another one is for any kind of maybe human factors tested or anything that you may have gotten out of the other file to know what kind of data would be needed going from one setting to another. But you certainly can use your own device as the primary predicate.

(John Beasley): Okay all right. Well I - so thank you very much. I was a little - still a little confused because it sounds as if it’s a split predicate in that case but I’m not really sure so maybe I should look at it a little further.

Marjorie Shulman: Right. No you have a - we could look at it further and I can further explain but it’s not necessarily a split predicate you’re just bringing in a reference device to show that this has been cleared for the other setting but...

(John Beasley): Okay Marjorie. Okay thank you very much. We’ll talk further.

Marjorie Shulman: Okay thank you.
Coordinator: Thank you. In our next question comes from (Rhonda Howell). Ma’am your line is open.

(Rhonda Howell): Hi. We - (Rhonda Howell) from IMDx, we were wondering that given the fact that you said it’s necessary to choose a predicate a primary predicate that will take you all the way through the flowchart.

Is there any advantage in FDA’s eyes to submitting with multiple predicates if you already have one that carries you through the flowchart?

Marjorie Shulman: No. That’s totally your choice in making your best showing of how your substantial equivalent to a legally marketed device.

If there is one predicate and that gets you all the way through that’s perfectly fine. We’re not insisting on multiple predicates.

It’s just if there are additional ones that maybe can help the FDA with the review and then we can maybe leverage any of that kind of information or look up a previous decision to see what kind of questions were asked that’s where it may be helpful but it’s certainly not a requirement. And plenty of devices go through the process with just one predicate device.

(Rhonda Howell): Okay thank you.

Marjorie Shulman: Thank you.

Coordinator: Thank you. And there are no other questions in queue at this time.

Irene Aihie: Thank you. This is Irene Aihie. Thanks again for participating and for your questions today. Please remember that the slide presentation, audio recording
and written transcript of this Webinar will be available on the CDRH Learn Web site in three to five business days.

For this and other regulatory information please visit our industry Web resources at Device Advice and CDRH Learned in the medical device sections of fda.gov. As always we appreciate your feedback. This concludes today’s Webinar.

Coordinator: Thank you. That concludes today’s conference. Thank you for your participation. You may disconnect at this time.

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