Coordinator: Welcome and thank you for standing by. At this time, all participants are in a listen-only mode. During the Q&A session, you may press star 1 on your touchtone phone if you would like to ask a question. Today's conference is being recorded. If you have any objections, you may disconnect at this time.

Now I would like to turn your meeting over to Ms. Anna Staton. Ms. Anna Staton, you may begin.

Anna Staton: Thank you (Stephanie). Hello, and welcome to today's FDA webinar on the medical device classification procedures proposed rule. I'm Anna Staton of CRDH's Office of Communication & Education.

This proposed rule makes changes to CDRH's reclassification process to conform to the new streamlined procedures required by the Food & Drug Administration's Safety & Innovation Act, or FDASIA.

Although it does not change the criteria, it does propose to clarify the criteria for Class III or high-risk devices. Today we have with us Nancy Stade, CDRH's Deputy Director for Policy. Following Nancy's presentation, we will
open the lines for questions. Please note this session will be recorded and posted to the CDRH Learn section of fda.gov.

Now I'd like to turn it over to Nancy.

Nancy Stade: Good afternoon. I'm Nancy Stade. Welcome to today's webinar on proposed revisions to 21 CFR Part 860, the CDRH's medical device classification and reclassification procedure proposed rule.

By way of background, this proposed rule covers classification and reclassification and call for PMA procedures for medical devices. As you know, classification, reclassification and calls for PMA processes are basic to our risk-based regulation of medical devices.

These processes were established by the medical device amendments of 1976, and that legislation also created the three regulatory classes -- Class I, Class II and Class III.

These three classes corresponds to level of risk and degree of control necessary to control the risks from devices. Importantly, since the medical device amendments, classification of a device can change through reclassification procedures as we gain additional information about the risks, benefits and level of regulatory control necessary to optimize the risk/benefit profile of a device.

In 1978, we implemented these procedures with 21 CFR Part 860. Again, this regulation makes certain changes to 21 CFR Part 860. But one important additional point by way of background, recent as you may know, FDA has been engaged in effort to finalize the classification...
Woman: (Unintelligible).

Nancy Stade: ...of all pre-amendment...

Woman: Are you getting ready to start your call or...

Coordinator: We've already started. I told her I would come back and help her once we got the call started because...

Woman: Okay.

Coordinator: ...she needs to see - get the slide.

Woman: But ask her if she's logged...

Anna Staton: Hey (Stephanie), I think we can hear you.

Woman: ...and just verify that she's using the correct information, the TW number and the participant passcode. It has to be in capital letters to accept.

Coordinator: Okay. Hold on.

Nancy Stade: Hi, I'm going to go ahead and continue. There seemed to have been some interruption, but I'm going to continue with this.

As a background, one additional point is that, as you may know, FDA has been engaged in an effort to finalize the classification of all pre-amendment Class III devices for which there's been no call for PMAs.
And what, you may ask, is a pre-amendment Class III device? These are the devices that were classified shortly after we gained authority over medical devices, for the most part, classified in the late 70s and early 80s into Class III, for which we never finalized the classification by calling for a PMAs - by calling for PMAs for these devices.

So why are we issuing this proposed rule now? Well the first reason is legislation in 2012. The Food & Drug Administration Safety & Innovation Act of 2012 made some significant changes to processes by which we reclassify devices and call for PMAs.

This renders some of our - some provisions in 21 CFR Part 860 out of date. So with this proposed rule, we're proposing to amend Part 860 to conform to FDASIA.

Another important reason that we're issuing this proposed rule now is that there's been significant amount of attention paid to our classification actions as we gear up and attempt to finalize the classification of all pre-amendment Class III devices. There's been a lot of activity in this area and there has been a lot of attention - come to our attention that there's a need for greater clarity in certain areas.

And the last point is Part 860 is overdue for an update. It was updated in 1998. In fact, there were some updates in 2008. But there has not been a significant revision to that regulation since it was performed - finalized in 1998. And when you consider how important classification and reclassification is to our basic regulation of devices, we think that an update is overdue.
So the first reason, we're implementing Section 608 of FDASIA. And as you know - as you may know from FDASIA, that legislation changed the basic process we follow when we're reclassifying a device or calling for PMAs.

Since 1978, that process was a Notice - since 1976 -- excuse me -- that process was Notice & Comment Rulemaking under the Administrative Procedure Act. FDASIA changed that a notice - to a Proposed & Final Order Process, but also made changes in the panel - in the panel requirement, changing that from a discretionary panel meeting to a mandatory panel meeting.

The - what is the effect of the changes going from a Notice & Comment Rulemaking Procedure to a Proposed & Final Order Process? Basically these are procedural changes intended to streamline the process of finalizing classification.

The effect of going from a rulemaking process to an order process is to eliminate the requirement of a formal economic impact analysis and also to take these classification out - actions outside of Executive Order 12866, which establishes administration review for certain regulations and certain other actions.

So the effect of FDASIA was to streamline the review, but also significantly it did change the panel requirement. And this - the Section 608 applied primarily to the following processes -- Section 513(e), which is reclassification; and Section 515(b), under which FDA must call for an approval action for a device classified into Class III.
But Section 608 of FDASIA also stated that not only made the change not only going from a rulemaking to an order process, but it also made a panel meeting mandatory for 513(e) and 515(b) procedures.

And what the legislation says is that we can affect a reclassification or call for PMAs by a final order. The final order has to be preceded by a proposed order and a panel meeting.

It doesn't say what order those two things have to occur, whether the panel meeting should precede or follow the proposed order. It just says both of those things have to precede the final order. In our proposed rule, we are going - we propose to retain this level of flexibility as to when the panel meeting occurs.

Secondly, major area of changes in 21 CFR Part 860 in the proposed rule is we propose to clarify the criteria for Class III devices. And what we are intending to do with this rule is to - this proposed rule is to provide greater clarity about the threshold criteria for classification into Class III.

And what do I mean by that? Well before you decide that a device is going to be in Class III, first you have to ask yourself these basic questions, and these are in the statute. And they basically amount to whether the device is high-risk.

The questions specifically are, is the device life-sustaining or life-supporting, is it of substantial importance in preventing impairment of human health or does it present a potential unreasonable risk of illness or injury.

So you have to ask yourself those questions first. And if the answer you get to is "No" on all three of those, then you're into Class II or Class I. You should
be looking at how you can appropriately regulate that device in Class I or Class II.

If, on the other hand, your answer to any one of these questions is "Yes," then you get to the second part of the statutory definition of Class III. And the second part of the definition is whether special and general controls are sufficient to control the risks for some - for such devices. And if the answer is "No," then you're in Class III.

But what we've found is this second component of the definition -- when are special controls and general controls insufficient to control the risks from some such devices -- has not been perceived as very clear, and there's need for additional clarity and additional specificity in when FDA may determine that special and general controls are not sufficient to control the risks of a high-risk device and justify classification into Class III.

So what we've done in those proposed rule is we've outlined greater specificity for when FDA may find that general and special controls are insufficient.

Now I want to be very clear, and I'll say this several additional times in the presentation, the point of this specificity is not to justify finding many more devices meet the criteria for Class III. The point is to provide greater clarity about when right now FDA may be finding that a device is appropriately classified into Class III.

So these are not intended to be new criteria, but they're intended to be more specific criteria that are already contained within the more general standard of when general and special controls are insufficient.
And so let me talk a little bit of each - about each of these five criteria. The first, devices that present known risks that cannot be controlled - so you may have a device that's beneficial - it's known to be beneficial, but it has some serious risks associated with it.

And to maximize the risk/benefit - to optimize the risk/benefit profile of that device, it may be appropriate to regulate that device as a Class III device, our highest level of control, to ensure that the risks are as well mitigated as possible for that device.

Similarly, devices for which the risk/benefit profile is unknown or unfavorable - so you may have a device where the information we're aware of does not establish that there's strong - that there's clinical benefit or may even suggest that there's not strong benefit in light of the high risks for this device. That's the second criterion.

The third criterion is devices for which a full review of manufacturing information is necessary, and this again is based on the statute. If you look at the provisions for PMA review and for PMA approval, it clear contemplates that FDA will be doing a review of manufacturing information in determining whether to approve a PMA.

In contrast, for 510(k) devices, there's a provision of the Food, Drug & Cosmetic Act 513(f)(5) that says we really shouldn't be denying a finding of substantial equivalence on the basis of manufacturing information.

So that level of control -- a full review of manufacturing information -- is appropriate for devices that are high-risk, and where it's necessary to have that review of manufacturing information to provide assurance that there is a reasonable assurance of safety and effectiveness. Similarly, devices for which
pre-market review of any change affecting safety or effectiveness is necessary - and again, this is based in statute.

If you look at the Food, Drug & Cosmetic Act 515(b)(6)(A)I, that provision states that you'll be - that FDA will require a supplemental application of PMA supplement for any device for which - for a change to a device -- a PMA device -- that affects the safety and effectiveness of the device. And again, contrast that with the 510(k) where we have a much lower standard for reviewing modifications to marketed devices.

The last criterion is certain combination products. And to be clear, this does not mean all combination products. And really, this provision of the proposed rule is really intended to be encompassed within the first or second criteria that I outlined above.

In other words, if you have a combination product where the risks are - where the risks can't be controlled at a lower level of regulation or we don't understand the risk/benefit profile -- perhaps because something about the drug or the biologics -- it may be appropriate to request a PMAs so we can require the degree of information we need to fully evaluate the risks and benefits.

So again, it's not certain combination products, but it's combination products where the type of PMA review is necessary to understand the risks and benefits of the combination product with the drug or the biologics.

Before I turn to the next slide, I'm going to say again these are - these criteria are not intended to change the Class III standard. They are intended to provide greater clarity about how we determine that a device is appropriately
classified in Class III because general and special controls cannot control the risks of a device that is a high-risk device.

Last point I'd to make in - about clarifying our criteria for Class III high-risk devices, this would not affect how FDA review 510(k)s because FDA reviews 510(k)s under the Substantial Equivalent Standard. This regulation is not proposing to change 513(i) which governs how we review 510(k)s.

510(k)s are reviewed by looking at the intended use of a device under review compared to a predicate and looking at the technological characteristics and the performance data. We do not propose to change those - to change the Substantial Equivalence Standard with these regulation, and so 510(k) process would not be affected.

The third reason for updating this rule now is we're seeking to improve predictability, transparency and consistency of classification actions. We believe a general update to FDA's Medical Device Classification regulation will increase certainty about how devices will be regulated, benefitting industry device users and FDA staff.

We note again that Part 860 has not had a general update since it was finalized in 1978. There have been updates in 1998 and 2008, but there has not been a major update looking at a number of the provisions we're seeking to update the terminology and the processes.

Since that time, our interactions with stakeholders have shown the need for greater clarity in the rule, particularly concerning criteria for classification and reclassification into Class III. And these interactions have include (sic) a citizen petition, they've included reclassification petitions, but they've
included legal and policy challenges to how we administer our classification authority.

In particular, I'll note a citizen petition that contested our use of certain forms that seem to eliminate the risk-based criteria from the Class III definition. We granted that petition and actually we updated those forms. But as you'll see, we're taking things one step further with the proposed rule, and we propose to eliminate those forms.

In addition, we would add some definitions that were not included or that were somewhat abbreviated and unclear in the current version of the Part 860. We've added to the definition of special controls, we've also included the definition of special controls guidelines and we've updated some of the terminology.

For example, 21 CFR Part 860 currently uses performance standards in many places where, due to changes in the legislation, it would be more appropriate to refer to special controls. Similarly, the current regulation refers to old and new devices. We more typically use the terminology "pre-amendment" and "post-amendment" devices, and we've made those types of changes throughout the regulation.

We just conducted an economic impact analysis of the rule and determined that it has no significant new burdens and is expected to have modest economic benefits. Of course this turns back to what I've said several times throughout this presentation, we're not seeking to change the standards for classification. We're seeking to clarify and provide greater specificity about what those standards are.
We do expect the rule to have modest benefits, just in greater clarity, and we hope avoiding some confusion about how we classify devices. So it has a modest - is expected to have modest estimated annual benefits.

The impact on panel meetings - it will implement the FDASIA requirement for mandatory panels to consider reclassifications and call for PMAs. It also clarifies that FDA may consult with a panel by telephone, but only for certain actions.

But that would be for the initial classification of pre-amendment devices - for example, unclassified devices where we think the issues are really not controversial or not significant and may be appropriate as a matter of resources to hold those panel meetings by telephone, similarly for discretionary panels for post-amendment devices and to consider certain reclassification petitions.

Importantly, the phone panel procedures will not apply to panels required under Section (513B) or 515(b). So those are the mandatory FDASIA panels - will not be affected by the phone panel procedures.

Lastly, we are looking for your feedback on the rule. The comment period will be open for 90 days. We do consider and address in the preamble every comment submitted on a proposed rule. We encourage the submission of electronic or written comments through the normal Notice & Comment Process. Specifics for submitting comments during the 90-day period can be found in the proposed rule.

If you're looking for a display version of the rule, it will - let me remind you it'll publish in the Federal Register tomorrow. You can find a display version
in the CDRH News section of our Web site. There will be a link to the display version.

So thank you very much for participating and you can send your questions to (danica@fda.hhs.gov.) or cdrhquestions@fda.hhs.gov.

Anna Staton: Hi (Stephanie). At this time, we'd like to go ahead and open the lines for questions.

Coordinator: Okay. Thank you. At this time, we will begin the question-and-answer session. To ask a question, please press star 1 on your touchtone phone. Please unmute your phone and record your first and last name clearly when prompted. To withdraw your question, please star 2. Once again, if you would like to ask a question, please press star 1 and record your name. One moment please for our first question.

And it looks like our first question is coming from Dr. (Jerome Farber). Mr. (Farber), you may begin.

Dr. (Jerome Farber): Yes, I just - in listening to the presentation - I haven't seen the slides yet - it - I guess I was confused about the nature of this particular webinar in terms of all medical and dental devices.

And it's - I haven't heard anything - I'm not clear about any actions that are related to Class II devices that have been on the market since the late 70s. Does any of the - I may have missed it, but does - do any of the changes and - refer to already-marketed and approved with 510(k) Class II devices?

Nancy Stade: So thank you for your question. And again, we are not making any changes to the 510(k) review process. These changes primarily affect reclassifications
and calls for PMAs. So the only way the - the way they could affect a Class II device would be if that device is subject to reclassification. We are not proposing to change the definitions of the three device classes. Those definitions remained as defined under the statute.

We are providing some greater clarity for Class III, but with this proposed rulemaking, we're not seeking to move any devices currently in Class II to Class III or devices in Class III to Class II. We are seeking to provide greater clarity on what the current standards are for classification into the three classes.

Dr. (Jerome Farber): Okay, thank you very much.

Coordinator: The next question comes from Mr. (Leroy Hamilton). Mr. (Hamilton), you may begin.

(Leroy Hamilton): Yes, thank you very much for the opportunity to ask a question. I want to thank Ms. Stade for her presentation and the attempts by the agency to clarify the requirements for classifying into various classes.

This has been a subject of some interest to me, and she mentioned that there had been one or possibly more citizen petitions regarding classification. As the author of one of those, I have an interest in this subject for quite some time.

She mentioned in passing that there may be forms eliminated, and I would some clarification. Which forms does she have in mind or does the agency have in mind to eliminate? Would those be Forms 3427 and 3429 or some other forms? Could you answer that please?
Nancy Stade: Yes. So on Slide 11, we refer to Form 3429, Classification Questionnaire, and Form 3427, the Supplemental Data Sheet. And both of those under the proposed rule would be eliminated. As you know, they were recently revised. The proposed rule proposes to eliminate them. We feel we can get the information without the need to rely on those forms.

(Leroy Hamilton): Well I'm sorry to hear that. The Classification Questionnaire has been around for a good long time and it seemed to be a useful tool when properly implemented because it provided an objective basis for anyone interested in the classification of a device to answer the questions. And until it was revised in July of 2012, it did so. It did guide one to the appropriate classification.

So it's interesting that the agency is leaning now toward eliminating these forms which were in use and they are defined in - the Classification Questionnaire is defined in the regulation. But thank you for the answer.

Coordinator: Our next question comes from Mr. (Luke VanHover). Mr. (VanHover), you may begin.

(Luke VanHover): (Unintelligible) for the update of the proposed rule. For a De Novo 510(k), which is a Class III device, where you will do a (unintelligible) classification to the Class II, would - is this falling under this proposed regulation and would it (unintelligible) to a mandatory panel meeting for a De Novo 510(k)?

Nancy Stade: So De Novos - the first determination when - for a De Novo is whether or not there is a predicate. If we decide there is not a predicate, then the device becomes eligible for De Novo classification under the standards in 513(a) which are further clarified by 21 CFR Part 860. There's - we are able to hold a panel meeting for De Novos, but we are not required to do so, and this proposed rulemaking doesn't affect that.
(Luke VanHover): Thank you.

Coordinator: Our next question comes from Ms. (Linda Meer). Ms. (Linda Meer), you may begin.

(Linda Meer): Yes, I was going to ask on the devices, I know used to - some people were using NDC numbers and now I think they're using product ID numbers. Can you still use NDC numbers for devices or is that totally ruled out?

Nancy Stade: The use of NDC numbers would not be affected by this regulation.

(Linda Meer): Or the device?

Nancy Stade: That's - this proposed regulation doesn't affect the use of NDC numbers.

(Linda Meer): Okay, thank you.

Coordinator: At this time Ms. Staton that appears to be all questions in queue.

Anna Staton: Okay, thank you (Stephanie).

Coordinator: You're welcome.

Anna Staton: This is Anna Staton. Thank you for your questions today. Please remember that this presentation will be available on the CDRH Learn section of fda.gov. The written transcript should be posted no later than Friday. And if you have further questions, please use the contact information provided at the end of the slide presentation. As always, we appreciate your feedback. Thank you for participating, and this concludes today's webinar.
Coordinator: Welcome. Again this concludes today's conference. You may disconnect all lines at this time. Again this concludes today's conference. You may disconnect all lines at this time.

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