FDA Webinar: Dental Devices Premarket Submissions

Moderator: Irene Aihie
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Operator: Welcome. Thank you for standing by. Participants are in a listen-only mode over the telephone lines until the question and answer session of today's conference. At that time, you may press star one on your touch-tone phone to ask a question.

Today's event is being recorded. If you have any objections, you may disconnect. And now I'd like to turn it over to your host, Ms. Irene Aihie. And thank you ma'am, 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.

A manufacturer who intended to market a dental device should conform to the regulatory controls in the Federal Food, Drug, and Cosmetics Act and the pre-market notifications requirement described in Title 21 Code of Federal Regulations.

During this webinar, members of the FDA will clarify the pre-market submissions process. Explain information to include in 510k submissions in order to avoid Refuse-to-Accept designations.

Clarify medical device reporting requirements, including how to report and who should report. And discuss and answer questions from webinar participants about the pre-market submissions for dental devices.

Today, Dr. Malvina Eydelman -- a member of the Division of Dental Devices here in CDRH -- will present an overview of the dental devices pre-market submission process. Following the presentation will open the line for your questions related to the information provided during the presentation. Now I give you Malvina.

Dr. Malvina Eydelman: Good afternoon. My name is Malvina Eydelman and I'm the Director of the Office of Ophthalmic, Anesthesia, Respiratory, ENT, and Dental Devices. I would like to thank all of you for joining us today.

The Center for Devices and Radiological Health has conducted phased implementation of reorganization to create an agile infrastructure that can adapt to future organizational, regulatory, and scientific needs.

CDRH has been piloting a more-integrated approach to device safety throughout the total product life cycle -- or TPLC as we like to refer to it -- since June of 2018. Although CDRH has applied a TPLC approach to the regulation of devices for many years, the reorganization will enhance communication among CDRH staff and enable more efficient activities across the life cycle, from pre-market review to post-market surveillance.

This slide depicts CDRH organization prior to the - prior to reorganization. Please note that pre-market review, post-market review, and compliance activities for the same devices were carried out in different offices.

The reorganization integrated CDRH pre-market and post-market offices across functions and allowed our experts to leverage their knowledge to optimize decision making. This type of structure consolidates and integrates many of the current aspects of the product review, quality, surveillance, and enforcement into a new, team-based approach.

From implementation of the new structure will increase information sharing across the Center, enhance collective decision making, and improve work-life balance and increase professional opportunities for our employees.

The new Office of Product Evaluation and Quality -- or OPEQ -- combines the offices of Compliance, Office of Device Evaluation, Office of Surveillance and Biostatistics, and Office of In Vitro Diagnostics and Radiological Health into one super-office focused on the total product life cycle approach to medical device oversight.

OPEQ has nine offices. Seven are product-focused, as well as two program-focused offices. Please note that the Office of Health Technology One -- our office -- is highlighted in yellow. This slide depicts the organization of our office.

Please note the Division of Dental Devices is one of the three divisions within OHT One, or Office of Health Technology One. Open design created a more-flexible organizational model that allows us to better adapt to changes in the regulatory environment over time.

We improved our efficiency -- as reflected -- by combining the compliance, pre-market, and surveillance programs within the same management chain. And driving decision making to the lowest appropriate levels in the organization.

We emphasize professional development and work-life balance in the structure to create a professional environment that supports long-term development of employees throughout a long career with CDRH.

We believe that our reorganization has added significant value to you, our customers. It allows for more straight-forward and streamlined interactions with CDRH. Provides you with a one-stop shop in many cases. Allows for better response to changing regulatory needs and new technologies.

And ease - ensures more consistent policy application across OPEQ, thus making it easier for you to know what to expect. Allows for streamlining decision making. And focus on professional growth and creating a better work-life balance for our employees.

Office of Health Technology One is your one-stop shop for all the questions relating to dental devices. We hope today's webinar is a beginning of our interactions with stakeholders and colleagues to support better regulatory outcomes, thereby improving dental health of US patients.

And now I would like Michael Adjodha -- the Acting Assistant Director -- to continue.

Michael Adjodha: Thank you Dr. Eydelman. Yes, my name is Michael Adjodha. I'm currently Acting Assistant Director for the Restorative and Surgical Devices Team.

My talk today will focus on reviewed challenges and opportunities in dental device 510k submissions. And after my presentation Dr. Nandkumar will present a post-market overview.

Before we begin the discussion of dental devices, I'd like to provide some background on the pre-market submission process. Each person who wants to market in the US a medical device intended for human use must submit a 510k. Unless a PMA - for which PMA's not required. Unless the device is exempt from the Act.

The 510k pathway is the most common pathway to market for medical devices. The 510k is a - not a form but a pre-market submission made to FDA to demonstrate that a device to be marketed is actually an effective -- that is substantial equivalent -- to a legally-marketed device. For more details on how to prepare a 510k submission, please see the relevant guidance document.

The 510k review process is shown in the figure. FDA's review time is 90 days, or 30 days for a special or third-party submission. Now there are two areas where the review process may stop. These are called "Holds". The first of which is at the Acceptance stage, where they can - an eCopy fee - eCopy Hold or a Fee Hold.

And also there's an RTA Hold at that stage. And again -- at the second stage -- is a substantive review stage or a substantive interacting stage. Or what we call the SI Stage. The total time to decision -- or TTD -- includes FDA time, plus time the sponsor takes to respond to FDA holds.

In this presentation I'll discuss common challenges at the RTA and SI stages, and best practices to help overcome these challenges. Now on to dental

devices. The types of dental devices FDA regulates as medical devices are found in Title 21 of the Code of Federal Register, Part 872.

The CFR can be accessed at the link shown. The CFR includes the following general types of devices. For diagnostic devices examples are caries detection devices or radiography devices.

For prosthetic devices examples include crown and bridge alloys and resins, composite resins, metal amalgams, cements, endosseous implants, root canal resins, bone grafting materials, impression materials, endodontic materials, et cetera.

For surgical devices examples include dental hand pieces, ultrasonic scalars, and bone plates. For therapeutic devices examples can include orthodontic appliances, treatment planning software, and anti-snoring devices. We also have other devices that are not in a specific - more specific categories. And those include curing lamps, dental operative units, dental ceramics, prophy paste, and of course toothbrushes.

Five ten K submissions -- as a predominant pathway to market -- represent the (unintelligible) workload. The division workload also includes pre-submissions, PMA supplements, 30-day notices, 513G submissions, and some IDEs.

We have a high volume of 510k submissions. A significant percentage of them are from small or foreign manufacturers. As you can see in the graph below, we average a large number -- 240 -- of 510k submissions a year.

We also have a high RTA rate for the first round, which is above 80%. And in the next few slides I'll be presenting some of the issues that we've found during the RTA process.

Of the 510k submissions we receive, most of our work concerns the following device types. The table here shows the top ten dental devices by number of devices cleared in calendar year of 2018. Note that this includes devices that were received in prior years.

The greatest number of submissions were for dental abutments and endosseous implants, composite resins, orthodontic aligners, snoring and sleep devices, dental ceramics, resin bonding agents or cements, the dental hand pieces, denture resins, and orthodontic software. The three letter code after the names on the slide -- the product on the slide -- represents the product code.

We can see a significant percentage -- about half of our workload -- revolves around dental implants and abutments. Also notable last year and this year are increasing numbers of clearances from snoring and sleep appliances, orthodontic appliances, and treatment planning software.

A number of devices have a total time to decision that is high and exceeds the goals established by our latest user fee optimization, also known as MDUFA Four. The top five are provided. The data for - is for devices that were received and accepted and proceeded to a final decision in 2018.

The current goal for this fiscal year -- which is now Fiscal Year 2020 -- is 116 days. As you can see, the total time for a decision -- or actually the average hold time -- is high for orthodontic software, dental hand pieces, snoring or sleep devices, endosseous implants, and dental abutments.

So we are working on identifying the causes and delays of this to minimize average total time of these devices. Now -- as I mentioned earlier -- the RTA rate is high for dental device submissions. We would like to accept submissions we receive as administratively complete. However, we continue to see challenges in one or more of the following areas that have presented this.

Referring to the RTA checklist sections, we often see deficiencies in device descriptions. We really see incomplete list of the device and each part for which clearance is requested. We see a lack of description of the engineering drawings or images of device. We often see incomplete lists of the alt-status of the components and accessories to be marketed with the device.

And we often see as the submission does not address the recommendations of a device-specific guidance. With regards to a substantial equivalence discussion, we often see predicate devices used inconsistently. And as a known justification provided if the predicate is not used in the testing. We often see a lack of discussion why any differences between your device and the predicate do not impact safety and effectiveness of your device.

With regards to labeling, instructions for use often do not contain communications or other information for professional use such as instructions, hazards, warnings, precautions, and contra-indications.

Per the other areas where we see deficiencies are sterilization -- where we often see incomplete information about sterilization and processing, including the method validation -- some of the insurance packaging and user instructions. And especially cleaning and disinfection methods.

Once we go after biocompatibility we often see a lack of biocompatibility testing or rationale for why such testing is not necessary. In that section we also see an incomplete material identification, which should include all patient contacting components including the additives. In addition, we can - the chemical identity is often not provided in a complete manner.

With regards to performance data, the test reports are often not provided. And sometimes specifications are given, but no results are provided. While often irrelevant or inadequate testing is done that fails to demonstrate how the data supports the finding of substantial equivalence.

And again, performance data often does not comply with the recommendations or draft the recommendations of an FDA-specific guidance. Or suggest an alternative approach.

Now, once the submissions are accepted for review, the second place the review process may be held is at the substantive-interactive -- or SI -- phase of the review. Performance statements and the selection of appropriate predicate continue to present the grievous challenges to clearance.

In this section I'll provide some suggestions for resolving these challenges. Once you've gone through performance statements, any statement of device performance or indication that could impact the evaluation of substantial equivalence will be evaluated.

New performance statements need to be supported with data. Performance statements that claim enhanced clinical outcomes will - may need to be substantiated with clinical data.

With regards to the primary predicate device, we recommend you choose a primary predicate device that's closest in intended use to your device. And secondarily, in technological characteristics to your device. Please use the 510k Notification Database to find an appropriate predicate.

Reference devices can be used for technological characteristics assuming there are no different safety and effectiveness questions not found in the primary predicate device. For a detailed description of this, please see the program guidance in the link shown on the slide.

Other -- excuse me -- other areas that hold - other areas where the review process may be held are performance data, biocompatibility, and sterilization. Suggestions for resolving these follow.

With regards to performance data, we suggest that you search 510k summaries of predicates to determine what tests were relied upon for equivalence. Those you can find in our database I mentioned in previous slides. We suggest you use relevant consensus standards. The link to our recognized standards is shown on the slide. You suggest you have the appropriate guidance. And the link is shown also on the slide.

With regards to biocompatibility, we suggest you conduct appropriate testing or provide a tox risk analysis for why testing is not necessary. Please see the guidance document with regards to conducting biocompatibility testing in conformance with ISO 10993 in the link on the slide.

With regards to sterilization and reprocessing, we recommend that you provide validated instruction that allow the user to properly re-process their device. I'd like to show you to the sterility guidance and the reprocessing guidance with links as shown on the slide.

Lastly, 510k summaries. This document is very often missing key information. We recommend that 510k summaries should be complete. Include a comparison of indications and technological characteristics, and why any differences do not affect substantial equivalence.

And include a brief description of the tests relied upon for substantial equivalence determination. And that - we recommend that you avoid absolute statements that your device is safe and effective, because the 510k process is based on substantial equivalence. So it is appropriate to say "as safe" and "as effective" to the predicate.

Your 510k summary should have the same indication for use as in your indication for use statement in your submission. And please check that your 510k summary does not contain trade secret or confidential information as this document will be posted on FDA's public database. And if you don't know -- if you're not sure -- of how to prepare a 510k summary, we recommend that you follow the good examples on our database of previous clearance.

Stepping back a higher - at a higher level, the following best practices will help include the quality of your submission and hopefully lead to a shorter Total Time to Decisions. We recommend that you follow an equivalent - a copy of the RTA checklist in your submission. And a link to that -- a sample checklist -- is provided.

When responding to an RTA or any deficiency, please indicate or highlight how and where the deficiencies have been addressed. Please see the deficiency guidance in the link on the slide. Again, as I mentioned in the previous slide please choose an appropriate predicate device. Search the 510k database for predicate devices within your proposed classification.

And also refer to 510k program guidance about the use of predicate devices and reference devices. Further, include summary tables of tests conducted, even if you include full test reports. Please see the relevant guidance about conducting non-clinical bench performance testing.

We recommend that you clearly explain the differences between your device and the predicate device and why the differences do not affect the safety and effectiveness of your device. It's very helpful if you provide text-searchable PDF files and that you proofread your final submission. And make - and assure consistency throughout your submission.

It's also helpful if you include your direct contact information and identify an alternative contact if applicable. In addition, I'd like to refer you to the following resources. Device Advice is a website that we have that is a wealth of information on the whole process of submitting a 510k submission as well as the total product life cycle.

We also have videos on CDRH Learn. And also like to refer you to DICE, who can provide assistance with your specific questions about how to market a device. As I mentioned, the 510k program and content guidances provide the framework for how to submit a 510k.

And in case you have specific questions about a device you intend to market, we recommend that you consult the pre-market submission guidance and submit a pre-market submission to the review division. And lastly we recommend that you contact the review division for specific questions.

Dr. Nandkumar will now present an overview of the post-market process.

Dr. Nandu Nandkumar: Good afternoon. My name is Nandu Nandkumar. And I'm the Acting Division Director for the Division of Dental Devices. In my portion of this presentation I will present an overview of post-market processes and consideration in the life cycle of a medical device.

I'll go (unintelligible) through the CDRH vision statement. It's to quickly identify poorly-performing devices, accurately characterize real-world performance, and facilitate device approval or clearance. Most importantly, our overarching goal is to ensure the devices marketed in the US remain safe and effective.

Medical device reports are an important source of information for the FDA regarding suspected device-associated injuries and malfunctions. Manufacturers, device user facilities such as hospitals, and importers are required to report events to FDA within certain time requirements through a standardized reporting mechanisms.

These reports include information about the device brand name, model name, serial and lot number, and a brief description of the event. FDA also receives voluntary reports by health care professionals and patients through the MedWatch website or the MedWatcher mobile app.

These voluntary reports can be anonymous if desired. Anyone can search the online manufacturer and user facility, device experience database, or the M-A-U-D-E -- MAUDE -- database to find mandatory and voluntary reports relevant to a specific medical device. And it can be an important and valuable source of post-market information.

In November 2018, Commissioner Scott Gottlieb and CDRH Director Jeff Shuren released a statement with an update to the medical device safety action

plan. And this statement included an ambitious new goal. Ensuring that the FDA is consistently first among the world's regulatory agencies to identify and act upon safety signals related to medical devices.

A critical piece of that goal in the safety signal management process, which occurs when FDA detects and receives a signal or indication that there may be a safety concern with the marketed device. So what is a safety signal? In 2016 CDRH issued a guidance document entitled Public Notification of Emerging Post-Market Medical Device Signals.

That document describes the signal as information -- which may arrive from one or more sources -- suggests a new potentially causal association or a note - or a new aspect of a known association between the medical device and an errant or a set of related events. That signal might justify or require further evaluation and or action by the Center.

A signal may also be specific to one device or extant to a class of devices. And a few examples are listed on this slide. The first step of the signal management process is signal detection. FDA continuously monitors and reviews many sources of data regarding medical device safety.

Most of the safety signals are detected or received from a few specific sources including medical device reports, post-approval studies, 522 post-market surveillance studies, device annual reports, and consumer complaints.

The second step of signal management is signal refinement, in which an FDA team conducts information gathering activities in order to better assess the signal. In the earlier stages of signal refinement -- after identification of the signal -- FDA will reach out to a manufacturer to communicate a potential, confirm, and request additional information or data if needed.

The team will also assess any additional real-world evidence available such as published literature and MDRs. During this stage the team is assessing characteristics of the signal such as likelihood and magnitude of the event, causal relationship, and potential for mitigation or alternative therapies. This helps to inform what potential FDA actions are appropriate or necessary.

The third step of signal management is developing an action plan. Examples of potential actions in the action plan are listed on this slide, and fall under regulatory actions and public communications. FDA may take one action, multiple actions, or none of these actions as appropriate for each signal.

In cases where public communication is planned, FDA will inform the manufacturers -- or the manufacturer -- shortly before issuing public notification, unless time does not permit because of the risk of patient harm or if it's not feasible. Public communications and information about certain regulatory actions -- such as device recalls -- are available on a - on the public FDA website.

In some cases, a signal may result in a market withdrawal or a recall. However, it's important to distinguish that withdrawal from the market may be for business reasons and does not always necessarily reflect a safety signal or a problem with the device.

In contrast, medical device recalls are done in order to address a problem with a medical device that violates FDA regulations. A correction action addresses a problem with a medical device in the place where it is used or sold. Removal action, which addresses a problem with the medical device by removing it from where it's used or sold.

Recalls are usually conducted voluntarily by the manufacturer and submitted via recall package to the FDA. FDA then classifies each recall as Class One, Two, or Three based on the perceived chance of serious health problems, injury, or death due to use of the device. FDA publicly communicates all medical device recalls. And information about each recall can be found in the medical device recall database in the public FDA website.

This concludes our presentation. And we will now move on to a question and answer session. And thank you for your attention. We also have a few other people -- other members of our Office of Health Technology One -- who will now introduce themselves. And they're available for the Q and A session.

Allison O'Neill: Hi, this is Allison O'Neill, Acting Safety Signal Coordinator.

Dr. Malvina Eydelman: Malvina Eydelman, still in the room.

Keisha Thomas: Keisha Thomas, OHT One Deputy Director.

Tiffany Palmer: Tiffany Palmer, MDR Reviewer, Analyst.

Dr. Malvina Eydelman: We also have a couple folks not from OHT One joining us today.

Diane Mills: Diane Mills, from the Division of Industry, Consumer Education.

Dr. Malvina Eydelman: Operator, we're ready for questions.

Operator: Thank you very much. So if you would like to ask a question, please press star then one. Please take a moment to unmute your phone if you did mute it, and record your name clearly when prompted. Your name is needed to introduce your question.

And if you need to withdraw your request, press star then two. But again, to ask a question at this time, please press star one and record your name. One moment please. Star then one, one moment please.

Our first question is from Marissa. Ma'am, your line is open. Go ahead and ask your question.

Marissa: Hi. I was just kind of curious to see if there was any plan to update the 2004 FDA guidance document on Class Two Special Controls for root form endosseous dental implants? And implant abutments.

Dr. Malvina Eydelman: So this is Malvina Eydelman. We have quite a number of guidances in the dental division. And as part of the reorganization we're taking a comprehensive look at everything that currently is available. And what's at different stages of revision. And finalizing our plan.

However, we hope to obtain input from all of our stakeholders -- such as yourself -- as to where you believe the need is. So we welcome your input.

Michael Adjodha: This is Michael Adjodha. Do you have any specific concerns or questions about that guidance?

Marissa: No. I was just was curious just to see if it's still, I mean if the agency still feels that everything in it is still relevant and applicable to what you are expecting to see in a 510k for those types of devices.

Dr. Malvina Eydelman: So in general if we believe that the guidance is no longer applicable we with draw the guidance. So by virtue of it being publicly available that means that we still believe that it is relevant to today's practices.

Marissa: Okay, great. Thank you.

Operator: Thank you. Our next question now is from Napoleo Monroe. And your line is open, sir.

Napoleo Monroe: Thank you. And we'd like to thank the group for helping the dental community understand the regulatory developments through this webinar and otherwise. Question comes to mind, how - what is the difference in the handling of an MDR and a - by the consumer -- by a patient -- and a consumer complaint?

Dr. Malvina Eydelman: And we're going to ask Tiffany to address this question.

Tiffany Palmer: Hi, this is Tiffany Palmer. Actually, with the reports from - that we receive from consumers, we accept anything they would like to report. It doesn't have to be a complaint per se. It could be whatever they feel they have a concern that they would like for us to address.

Napoleo Monroe: What level of information are you receiving back in the - from the dental community or dental patients? I - in the real-world evidence follow-up? In the signals?

Dr. Malvina Eydelman: So I believe Nandu -- Dr. Nandkumar -- was trying to delineate the difference of the definition of the signal versus MDRs. And I'm going to ask Allison to highlight the difference.

Allison O'Neill: Sure. So a safety signal can come from multiple sources. And MDRs are certainly - they can act as the source of the signal. And it's also a source of

information that we look into for any signal when it comes in through any source.

And we would also look for information that we could obtain from the dental community -- from real-world evidence, as you mentioned -- and we would assess the totality of the evidence when deciding on the action plan how to address that signal.

Keisha Thomas: In addition to -- hi, this is Keisha Thomas -- in addition to MDR information, we also solicit and encourage any type of information that you have. Doesn't have to necessarily be in the form of a complaint.

But any information that you have that you think it is important that the agency look into, evaluate, and review. And we also take that information and we funnel it into our signals process as well.

Napoleo Monroe: Thank you very much. And thank you for informing the dental industry in this and other presentations.

Operator: Thank you. Our next request now is from Tom Kelley. Sir, your line is open.

Tom Kelley: Hello. And I want to say thank you again for what you have. I just had a quick question. We are in a -- excuse me -- in a process of doing a 510k submission. And I do have a question.

If I have - I've got the contra-indications for use and that's going to go on a label box. But what I'm thinking about is how would you like to address it on the individual component that gets - you want to have a slight See indications for use for contra-indications on an individual packet? Or is just being on the label box sufficient?

Michael Adjodha: Hi, this is Mike Adjodha. If I understand you have a device that has multiple components and you want to know whether each component needs to be labeled with the indications for use, is that correct?

Tom Kelley: Not quite. It's one component. But there - it's like, you know, a pack of 100. So you've got basically individual units. So do I have to label individual units with the contra-indication?

Michael Adjodha: Why would you have a pack of 100 - is this one device that's being shipped to the end user with 100...

((Crosstalk))

Tom Kelley: Yes, with 100 uses. Yes.

Michael Adjodha: A hundred uses.

Tom Kelley: Yes.

Michael Adjodha: It's on the - it should be on the outside package, right?

((Crosstalk))

Tom Kelley: It's only on the...

Michael Adjodha: ...individual...

Tom Kelley: I just want to know if I need to put it on the inside package?

Michael Adjodha: My understanding is - group is saying No.

Tom Kelley: Okay. I just wanted to make sure. Okay. That's - that was the...

((Crosstalk))

Tom Kelley: ...question. So I just wanted to see how to address that. So...

Keisha Thomas: As long as it is on the packaging -- the ultimate outer packaging -- by which all of the components are being...

Tom Kelley: Right. Yes...

Keisha Thomas: ...in. That's enough. You would not have to package each individual component within that larger packaging.

Tom Kelley: Okay. That's perfect. That's what I wanted to make sure. Thank you very much.

Operator: Thank you. Now our next question is from Sonny Bocala. Sir, your line is open.

Sonny Bocala: Hi. Great presentation, I enjoyed it. And I appreciate you guys taking the time to give us this information. My question is regarding the 510k for sleep apnea devices.

For sleep apnea devices that have not received the 510k -- or that are undergoing FDA review -- is there any repercussions if they're already out to market and they're being marketed for the claims of sleep apnea? And it's already being used in the public before it receives a 510k?

Dr. Nandu Nandkumar: So, you know, these devices can be indicated both for snoring and sleep apnea. And if you had obtained clearance or if you were under enforcement discretion or exemption from pre-market notification for snoring, then you should be only indicating it for snoring.

If you do intend to add obstructive sleep apnea as an indication in - as far as I know, most of those devices are Class Two - most of them are Class Two 510k devices. So which would require a pre-market notification or a clearance - and a clearance by the FDA before you market it for OSA.

Sonny Bocala: Okay...

Keisha Thomas: And so what I'd also like to add is that if you are indeed marketing them for those indications that have not yet been cleared or approved, you should stop that. Or at least at a minimum contact the agency regarding your submission.

And have a conversation with us about where that line needs to be drawn and whether or not the actual indications that you are out there making that are still under review are such that we would you to stop marketing the device. So I would say contact the Review Division. We are a friendly bunch of people.

Pro-activity is probably the wiser choice in this realm. And we can have a conversation with you and actually help you identify whether or not it is claims that need to stop being marketed and what happens in that process.

Sonny Bocala: Yes. I've already received a 510k, but I am seeing a significant amount of marketing being done by companies that don't have FDA approval on any of

their marketing pieces. But they do have claims for OSA and sleep apnea. So my understanding...

Keisha Thomas: Oh...

Sonny Bocala: ...is that that was not allowed to happen. But I'm seeing a significant amount of it happening. And I just didn't know if had - if regulatory had changed.

Keisha Thomas: No. So you are correct, that has not changed. And if you are seeing that and they're out there more than likely we are not seeing that. So at any time we actually do solicit and request allegations and complaints to the agency to make us aware of what we cannot see.

There is a mailbox -- I believe it's O-C-medical device complaints at FDA dot HHS dot gov -- and you can send that information to us. It can come anonymously. It can come with your information. We would keep any information from where the complaint came from fully anonymous inside of the agency.

But we actually do welcome those types of communications to the agency. Because we can't always be everywhere and seeing everything that's being promoted on the web. And so we actually do welcome, you know, consumes and industry to actually reach out and make us aware if you're seeing that. So you are not incorrect. That practice is not allowed.

Sonny Bocala: Can you say that website again please?

Dr. Malvina Eydelman: Why don't you send an email to DICE and then you'll get an answer in writing so that there is no question.

Dr. Nandu Nandkumar: Yes. And if you go to Google and type CDRH and allegations, the first site that pops up is Reporting Allegations of Regulatory Misconduct to FDA. Okay.

Sonny Bocala: Okay. Perfect. I appreciate that.

Operator: Thank you very much. Now our next request is from Stuart Goldman. And your line is now open.

Stuart Goldman: Thank you very much. That was a great presentation, especially earlier on with the most devices the dental branch typically sees and how long they take. But anyway, my question is with respect to dental implant submissions, product code DZE. And the issue related to the associated manual surgical instruments that typically go with these devices to the end user.

And of course those instruments are Class One exempt under product code NDP, which these instruments are briefly referenced typically in the surgical procedure for the implant.

And in a recent submission we got some feedback from the FDA that the instruments -- if they're supplied in a tray under product code KCT -- well, that product needs a standalone 510k -- that being the tray under product code KCT -- to hold the accessories, which are Class One exempt under product code NDP.

Which all are part of, you know, the dental implant system that the manufacturer typically sells or supplies to their end user. So there's another 510k that needs to be applied for, for these cases to hold the instruments.

Tiffany Palmer: So you're saying a convenience kit with exempt products, you're being asked to submit a 510k for that?

Stuart Goldman: No, they're not convenience kits. On a recent submission for a dental implant system the question was raised about - so you've got instructions for how to clean and sterilize the manual surgical instruments, which are accessories to the dental implant. As a Class One 510k exempt device.

But those instruments are typically supplied in a case. And a case needs a 510k clearance under product code KCT. And so it is, you know, it kind of caught us by surprise now that we have to relay that information to our client that if you want to sell these instruments or supply these instruments -- because they're - a lot of them are typically given away with the implant - with the dental implants -- you need a 510k now for this sterilization box to hold your instruments.

Which are Class One exempt. That they're giving away, which are dental implants and abutments typically.

Dr. Nandu Nandkumar: So can I respond? Yes, so this - your question appears to be a very specific issue that I don't think we can go into in depth at this time. Can you please send me your confirm in an email to my email address? This is Nandu Nandkumar. Or you can also send it to the DICE email, which is at the end of this presentation. Okay?

Stuart Goldman: Yes. And I could send it to you, and I have your email from previous communications. So thank you for that.

Dr. Nandu Nandkumar: Good, thank you.

Stuart Goldman: Okay.

Operator: Thank you. Now our next request is from Ted Clayborn. Your line is open.

Ted Clayborn: Yes, hi everybody. And thanks for the presentation and your time. I see you reported a pretty high RTA rate. And there's some long additional information holds.

I wonder if you're - you think that the submissions -- the quality of the submissions -- is poor and that's why you're suggesting certain things to look at in those submissions? Or if there's some internal processes that you could look at -- or you are looking at -- to improve those numbers?

Dr. Malvina Eydelman: So hi. This is Malvina. You know, the beauty of having a TPLC office is it's a -- like I said -- it's a one-stop shop. So at the office level we have been looking at all of the different devices within our shop and trying to figure out what are the reasons for increased TTD.

And then there was no exception, we've been analyzing it, been stratifying it. Having said that, I want to - part of doing this webinar is to make sure that all our stakeholders understand that the only way to resolve it is if we work together. I don't think a one-sided solution will really help us resolve this.

I don't think it's all on FDA and I don't think it's all on the sponsors or submitters. I truly believe that this is just the beginning of the conversation. We're doing new internal analysis. We're hoping that by sharing our knowledge and establishing very fluid and dynamic communication channels we can answer as many questions as we can, and that together, reduce this TTD.

Ted Clayborn: All right, thank you.

Operator: And thank you. Now our next from John Cogan, your line is open.

John Cogan: Hello. And thank you very much. I have a question. We - I have noticed a similar - in touch with a similar device manufacturer. He got an exemption, a medical device data system - for a medical device data system.

Now the device I am looking at getting regulated is similar to that. How do I - and I suspect I would look for an exemption. How do I find out about that? Or how do I start that process?

Dr. Nandu Nandkumar: So I'm just going to paraphrase or repeat your question just to make sure I understood it. So you're saying that you have a product that you think could fall under the - a medical device data system. And you want to know from us if that is correct? Right? Is that what you want?

John Cogan: Exactly...

Dr. Nandu Nandkumar: Okay...

John Cogan: ...yes.

Dr. Nandu Nandkumar: ...I would - yes, I would recommend the pre-submission process if you want our feedback. That is the best way to do that. Are you aware of our pre-submission guidance and the process?

John Cogan: Am I - well, I -- sorry -- am I available? Of course I am...

Dr. Nandu Nandkumar: No, are you aware? Are you aware of the...

John Cogan: Oh, yes. Sorry. Yes. Yes.

Dr. Nandu Nandkumar: Okay. Yes, so I would submit the pre-submission. And then if this is a dental product it - that pre-submission will come to the dental devices division and we will provide the feedback through that process. Okay?

John Cogan: Thank you very much.

Operator: Thank you. Now our next request is from Chris McKee. Your line is open.

Chris McKee: Hi. Thank you very much. So going back to an earlier question regarding the - any potential updates for some guidance documents related to endosseous dental implants.

On that same kind of topic, is the FDA planning on releasing any type of additional guidance documents for more recent kind of technologies related for, particularly like dental implant systems? Namely things like overdenture bars that connect to abutments versus implant connections, digital workflows, as well as dental laboratory controls and those types of things?

Dr. Malvina Eydelman: So -- this is Malvina again -- I just wanted to point out that in addition to guidances, there is a small confirmation that's available on our website. And I hope that you and everybody listening utilizes it to its max capacity.

We have a digital web page that is continuously being updated that has all of the guidances and recommendations and examples, et cetera. In addition, we have been actively working to revamp our dental web page. And it's continuously undergoing processes.

So while we can't tell you what guidances we are about to release until they are released, we can tell you a lot of other information. And we try to continuous to - we actually have quite a large team working on the dental web pages. And we're continuously updating it with anything that we feel comfortable sharing publicly.

However, in addition to that I just want to reiterate one more time that we really do want to hear about the needs in the community. Because the goal for the web page is to help communicate the information that all of you are looking for. So please continue communicating through DICE. And then they will communicate to us about the needs in the community.

And we intend to communicate everything that we can through the web pages. Or to modify our plans for our guidance development to address those needs.

Chris McKee: Okay. Yes, thank you. It just seems like we've, you know, for several years now we've been kind of in a somewhat of a black hole from an industry standpoint on what FDA's interpretation is with some of these devices.

And you know, we don't know. Some of them have been around for years but we don't really know how to do anything as far as classification. Because the classification codes are very generic and I'll say have many gaps in them based on current technology.

And so it makes it difficult for industry to be able to know how to move forward with new production introduction to treat some of these patients with some improved technologies.

Dr. Malvina Eydelman: So as I've pointed out, we have just undergone a significant reorganization so there are a lot of new people getting this input. So I personally would greatly appreciate if you could consolidate your thoughts and send it to DICE so that we can receive it in writing and process it accordingly.

Chris McKee: Great, thank you.

Operator: Thank you. Now our next request is from Marissa. Ma'am, your line is open.

Marissa: Hi. This may be kind of reiterating what the previous question was. But I was hoping with everyone that was there we could get a little more guidance on what exactly are - the agency looking to have in the intended use statement for the dental abutment systems and implants in regards to specifically compatibility with other devices and things like that?

Michael Adjodha: Yes, we'd have to get with our subject matter expert and get more specifics about what you're - to address your concerns. As we mentioned previously, can you pose that in terms of an email and maybe send it to Dr. Nandkumar or DICE? And then we could analyze it and provide you the appropriate feedback.

Dr. Malvina Eydelman: And also clarify whether your question is intended to be broad, or if you're really interested in specific question about your submission. Because it might be easier to answer if it's submission-specific.

That we can generate right away. Because it depends on the content - on your device and the content of the submission. And generating broad answer usually requires a lot of input to make sure we didn't forget anything or that we're comprehensive.

Marissa: Absolutely. And I was just looking at it in a high-level. Because as I've seen through the years with the 510k approvals for these types of products and product codes, the intended use statement has shifted greatly.

And so I just kind of want to make sure I have a clear understanding of what is expected other than who, you know, stating the intended population and the typical things that are found in the intended use statement. What was the email to ask the question to again?

Dr. Malvina Eydelman: It's on the last slide. DICE at -- D-I-C-E -- at FDA dot HHS dot gov.

Marissa: Great. Thank you so much.

Operator: Thank you very much. Again, if you would like to ask a question please press star then one and record your name clearly. One moment please.

((Crosstalk))

Operator: We do have one more. Hannah...

Irene Aihie: We'll take one more question...

Operator: ...we have one more. Hannah, your line is open now.

Hannah: Hi. I have a question. So the NDP -- which is Class One -- also covers trial abutment. How you guys define trial abutments versus temporally abutments?

Dr. Malvina Eydelman: I'm sorry, can you repeat the question?

Hannah: How do you guys define trial abutments, that is classified as NDP Class One?

Dr. Malvina Eydelman: I believe that's the kind of question we would prefer to answer in writing. So please forward your question to Dice and we'll respond to you in a written form.

Hannah: Okay. All right, thank you.

Operator: Thank you. Our next now from Madris Tomes. Ma'am, your line is open.

Madris Tomes: Thank you. So some companies consider device materials and alloys to be a trade secret. But you had stated not to included trade secret info in the 510k application.

So I'm wondering how consumers -- or even you folks -- can identify what materials are being used? And I ask because I've seen a lot of reports recently for metal allergies and failure to osseointegrate.

Michael Adjodha: Yes, Michael Adjodha. My comment was with regards to 510k summaries. For that you should not include trade secret information in the summary. It does not apply to the submission itself. We expect to see the confidential information in the submission itself. Is that your concern, with the submission? Or is it the summary?

Madris Tomes: Well, so I misunderstood and I thought that you meant that in the 510k application. So I wasn't sure...

((Crosstalk))

Michael Adjodha: No, just the summary, which is a public document.

Madris Tomes: ...evaluate materials. Yes. So but I guess I still am wondering if - is that the type of information that would be redacted from the summary that's available to the public?

Michael Adjodha: Well the summary should not have to be redacted, because everything on there should be publicly - it should be for public consumption.

Madris Tomes: Okay.

Michael Adjodha: So we make sure once we - we post the summary that there's nothing on there that is considered a trade secret.

Madris Tomes: Okay. And do you know if the - if that material and the alloy changes -- if it goes from titanium with nickel to titanium with a different compound -- is that something that requires a new 510k? Or can that just be changed by the manufacturer?

Michael Adjodha: Well we - there's a guidance document on when to submit a 510k for changes. We recommend that you refer to that. It basically is

Madris Tomes: Oh...

Michael Adjodha: ...up to you. You have to do a risk analysis to determine if the change can affect the performance of the device. So it's up to you to determine that.

Madris Tomes: Okay. All right, thank you.

Operator: Thank you very much. Our next question now is from Brian Melkin. Your line is open.

Brian Melkin: Hi. Can you hear me? So the question I have is about the 510k database in general. So there was a comment made earlier today that, you know, that the most appropriate predicate isn't always located by the database. It has some prior codes in it, you know, it has product names.

But it doesn't have a search feature for looking for specific features of devices. Is that a feature that FDA plans to add to the database at all? Because there are third-party providers that make these databases, but I've spoken to them they're fairly expensive. It's like 20,000 to $30,000 to get these subscription fees per year. So - which my firm doesn't subscribe to. And other firms I've been at has not been willing to pay those fees.

But it would be helpful if FDA could make something like that more available. And as a follow up question too, in terms of you mentioned that there were 510k models that were available. If you could provide some links to that?

And also in terms of summary review. Sometimes there are very limited options I guess in terms of third-party providers like FOI Services that may or may not have those 510ks. And otherwise going through a FOIA request can take months if not years to sometimes get those documents. And it's a very frustrating for industry to find those examples.

Dr. Malvina Eydelman: So I'll start. You know, FDA overall is continuously looking at our IT infrastructure and trying to delineate how we can keep being modernized with the budget at hand. And where to - where the resources are

most needed. So I can't tell you specifically when and if that feature is coming to the computer and you, so to speak.

But I do think it would be very helpful if you submit your comment in writing to DICE. Because those get forwarded to the folks who are making the decisions about which features to add to our data system next. And what warrants resource allocation.

Michael Adjodha: With regards to good examples, in my presentation -- this is - sorry, this is Michael Adjodha -- I was referring to good examples of 510k summaries in our database. We don't have posted 510ks from database. Those are trade secrets. And so if you -- you're right -- if you wanted to get a copy of a 510k you would have to go through an FOI and be redacted and it could take a significant amount of time.

But we're - we have made efforts to make sure our 510k summaries are pretty comprehensive. So I encourage you to look at those and look at good examples to know what the predicates have in their submissions.

Brian Melkin: So again, where is that - where would submit those comments to? You said for the IT infrastructure?

Dr. Malvina Eydelman: So everything goes to DICE. D-I-C-E at FDA dot HHS dot gov. They're sort of the hub that collects all the questions and the comments and then disseminates it throughout the Center according to the expertise that it warrants. But I believe Nandu had another comment.

Dr. Nandu Nandkumar: Yes, I just wanted to add a couple of things too. If you're trying - if your question is that if you're trying to search for a good example or a predicate device, there are a couple of other databases that you can. There's

also the registration and listing database and the product code database and the 510k database.

Between these three databases you can go back and forth and try to find the appropriate product code where your product would fit into. And then search the 510k database in that product code that you think is the best fit.

And like Michael said earlier, the more recent 510k clearance is in a new product code that you would find - would have more comprehensive and summaries or examples of good 510k summaries. And that'll be like a best practice, or...

((Crosstalk))

Brian Melkin: Well that's true, but it doesn't give you product features. So if you're looking for specific product features, you know, other kinds of databases you can go in and search and put in whatever it is you're looking for. Like certain composition or metals or, you know, whatever it is that you're looking for in that device.

Product names aren't very descriptive a lot of times. And then going through each and every one of them can be very time consuming, even once you get all those product codes. So that's...

Dr. Nandu Nandkumar: Yes...

Brian Melkin: ...I guess that what I was requesting could be...

((Crosstalk))

Dr. Nandu Nandkumar: We understand that and...

Brian Melkin: ...I'll put a comment into DICE about that.

Dr. Nandu Nandkumar: Yes. Yes...

Brian Melkin: It's nothing new. I mean I spoke - I've spoken to people before at DIA and other conferences. And basically the FDA reviewers say well the best thing to do is to Google and find sort of the best device and then, you know, from that. But Google doesn't always catch everything, right.

So it's - there are things that are reviewed that may not go through a Google search where you're finding sort of the best or most similar product to the one you're trying to find. And then in terms of the redactions, I know -- I used to work at FDA -- so on the drug side there was a lot of push back in the early 90s about making some of the summary reviews more comprehensive.

And I think also making them available. But obviously now that they are available -- through Drugs at FDA -- it provides a really valuable resource. And so I'd recommend that the Center consider doing something more comprehensive like that.

Irene Aihie: Thank you. We'll...

Brian Melkin: Thank you.

Irene Aihie: ...now take our next question.

Operator: And our next is from Ralph Anderson. Your line is open.

Ralph Anderson: Okay, hi. This is Ralph Anderson. I had a question about 510k third-party reviews. During the presentation you had mentioned that there's a 30-day time frame for third-party reviewers? And I was wondering if this is a commonly used pathway for dental products?

Dr. Malvina Eydelman: So third party review is definitely an asset that sometimes is not fully utilized. And actually one of our strategic goals for the office is to take a broad strokes look and to see if there are other proponents that would be comfortable with sending to the third-part reviewers. So it...

Dr. Nandu Nandkumar: Yes. And this is Nandu Nandkumar. Just to add to that, there are dental product codes that are currently eligible for third-party review. So - and we do see them. So yes. So if you're - have a device that is eligible for a third-party review, that does not have clinical data in it. And then you can consider that pathway.

Dr. Malvina Eydelman: But in addition, if you would like to propose some of the pro-codes which you believe would be helpful to be reviewed by third party, I personally would be very interested in hearing these comments. So again, if you can gather your thoughts and send an email we would greatly appreciate your input.

Ralph Anderson: Okay, thank you.

Operator: Thank you. And our next request is from Valerie Simenewski. Your line is open.

Valerie Simenewski: Hi. Thank you. I wanted to ask - this is related to 510k equivalency. If a company adequately substantiates equivalence to a competitor device through

a 510k and the intended use is the same, can we leverage claims from the equivalent device that has been on the market for a number of years?

Michael Adjodha: This is Michael Adjodha. Well it depends on your device. I mean you can leverage performance statements if your device has the capability of doing the same thing as the predicate device.

If the predicate device has some additional features you don't have, then you would not be able to have the same performance statements. And also it could be that the predicate device expanded their indication after FDA clearance without our knowledge.

And so it's always best to check the database to see what exactly was the original indication or 510k summary for that device. It is often on - in the claims or performance statements that happens after - unfortunately after we clear a device.

Valerie Simenewski: Okay, thank you.

Operator: Thank you very much. Our next question now from Ted Clayborn. Your line is open, sir.

Ted Clayborn: Yes, hi. Thanks for letting me ask another question. Dr. Nandkumar had mentioned Q-subs, so I just wanted to ask more about Q-subs. I wonder if you could comment generally about your expectations on when you expect Q-subs and how much detail you expect in Q-subs?

It seems to me sometimes they border almost on a pre-review. So I just wondered if you have any comments on that.

Dr. Malvina Eydelman: So I'll start and then I'll let Nandu continue. In general, if you have to ask whether I should submit the Q-sub, the answer is you should. You know, we really want to encourage pre-submissions.

I believe that they make for ultimately much higher quality submissions, assuming that our feedback is utilized. We work very hard in providing timely feedback. We meet with everybody who requests an in-person meeting. We intend to stick behind our answers.

So from people who have done the pre-subs, I have never heard "I wish I didn't". But from those who never did, I often hear "I wish I did". So again, it's sort of simplistic but if you have - if the thought has crossed your mind then the answer is yes, you should submit a pre-submission.

And as far as the amount of information, in general the more specific your questions are the more specific our answers will be. We do not pre-review the information however.

Dr. Nandu Nandkumar: Yes, I think Malvina pretty much said it all. And this is Nandu here. I just want to add that we typically do not review data in pre-submissions.

So other than that, if it's a test protocol or any other device issues -- performance statements and the necessity of whether data is - what type of data is required, those kinds of discussions are what we see in pre-subs. And like Malvina said, it - we will strongly recommend that, a pre-submission for these types of discussions.

Ted Clayborn: All right, thank you.

Operator: Thank you very much. Our last request now is from Madris Tomes. Ma'am, your line is open.

Madris Tomes: Thank you. My question is about the alternative summary reports. The adverse events that were recently made public. I saw that there were 2.1 million adverse events submitted for dental implants. And the outcomes of those haven't been made available.

So for instance I can see that the device you know, failed to osseointegrate. But what happened to the patient after is being redacted. And the reason I bring that up is because there were 20 to 30 different companies that had submitted those over the years. So if they're using a device as their predicate that has all these events that couldn't be seen for the last 20 years, how can they learn from each other's issues and - without those outcomes?

So I'm wondering if there's a way to make those publicly available so that the companies can realize Oh, well I didn't realize that the predicate I used had, you know, 400,000 adverse events that were serious injuries.

Dr. Malvina Eydelman: So obviously the number of events was very high. And internally we are taking a deeper dive and trying to identify lessons learned. And develop a plan forward. We're in the midst of that process.

And part of that process is identifying ways to communicate our findings and our recommendations. And we're going to be taking a number of avenues to do that. Our web page will be one of the ways. So we'll look forward to sharing with you lessons learned in the near future.

Madris Tomes: Okay. Do you know if those will be discussed at the bio-compatibility metals meeting that's going to be happening in November? That might be a good

place to communicate that out. I mean, if - depending on timing, of course, for you.

Dr. Malvina Eydelman: I don't believe so. That is a very full agenda and there is quite a number of other topics that the time will be allotted for.

Madris Tomes: Okay. All right. Thank you.

Operator: Thank you very much. As I have no further questions in queue I'd like to turn the event back over to Ms. Aihie for any closing remarks.

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 W-W-W dot F-D-A dot gov forward slash Training forward slash CDRH Learn by Thursday, October 10. If you have additional questions about today's presentations, 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 live webinar please complete a short, 13-question survey about your FDA CDRH webinar experience. The survey can be found at W-W-W dot F-D-A dot gov forward slash CDRH Webinars immediately following the conclusion of today's live webinar.

Again, thank you for participating. This concludes today's webinar.

Operator: And as today's event is concluded, again thank you for your participation. You may please go ahead and disconnect at this time. Thank you very much.

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