FDA Webinar: Quality in 510(k) "Quik" Review Program Pilot

Moderator: Irene Aihie
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Coordinator: Welcome and thank you for standing by. At this time all participants are in a listen only mode until the question and answer session of the call. If you'd like to ask a question during that time, please press star followed by number 1. Today's conference is being recorded, any objections you may disconnect at this time. Now I'd like to turn over the meeting to Irene Aihie, you may begin.

Irene Aihie: Hello and welcome to today's FDA Webinar. I am Irene Aihie, a CDRH's Office of Communication and Education. The Quality in 510(k) ("Quik") Review Program provides an alternate method to submit a pre-market notification (510(k)) to the FDA using the eSubmitter software to format the submission. The purpose of the Quik Review Program pilot is to evaluate the Quik Review Program and where the use of the FDA's free eSubmitter software is to produce well organized submissions that can be used more efficiently to help promote timely access to safe, effective and high-quality medical devices.

Today, Angela DeMarco, bio-medical engineer from 510(k) Staff within the Office of Device Evaluation here in CDRH will present an overview of the

program. Following the presentation, we will open the line for your questions related to the information provided during the presentation. Additionally, there are other Center subject matter experts here with us today to assist with the Q&A portion of our Webinar. Now, I give you (Angela).

(Angela DeMarco): Thank you Irene. Today I will be presenting on the Quality in 510(k) or, Quik, Review Program pilot. During this presentation we will discuss the purpose of the pilot, background on how the pilot was developed and changes compared to the current 510(k) process.

At the end of this training, you should be able to determine eligibility into the quick review pilot, how to prepare your 510(k) using eSubmitter and know what to expect from the review process.

The purpose of the Quik Review pilot is to simplify how manufacturers complete a 510(k) submission for their moderate risk medical devices, and to evaluate whether use of eSubmitter will result in well-organized submissions that can be reviewed more efficiently.

Periodically the FDA initiates pilot programs to help reduce the total time to decision and to improve consistency and efficiency in 510(k) review. Products are chosen for this pilot program by the review groups. They identified certain products they believe can be reviewed in a more efficient manner than the Traditional 510(k) pathway.

The eSubmitter template being used for this pilot has been updated based on experience from the 2014 eSubmitter pilot. Quik stands for Quality in 510(k). Well understood products means that these products can be reviewed in an efficient manner while still maintaining safety and effectiveness. The eSubmitter application is software downloaded from the FDA Website., The

software format packages and validates the submission, but does not submit it to the FDA.

An eSubmitter template is a template located within the eSubmitter application. It is used to construct the submission. The Quik Review Program pilot includes only Traditional and Abbreviated 510(k)s that meet the eligibility criteria of the program, which will be discussed in the next slide.

The following are not included in this pilot and are considered outside the scope of the pilot: Special 510(k)s, in-vitro diagnostics, and biologic products.

In order to be eligible for the pilot program, the 510(k) must meet all of the following criteria. Failure to meet one will render the file ineligible.

The primary product code must be on the pre-identified list of product codes, this list can be found on the Quik Review Program pilot website link at the end of this presentation. Secondary product codes may be used but the primary product code must be on the list.

The 510(k) must be constructed using the "CDRH, Non-In Vitro Diagnostic Device – 510(k)" eSubmitter template. There are several templates available through eSubmitter. For the Quik Review pilot the CDRH Non-In Vitro Diagnostic 510(k) template must be used to be tracked properly.

The product cannot be a combination product, this includes device-drug and device-biologic combinations. Combination products can confound and complicate the review, especially if consult to another Center is needed. We do not believe that a combination product can be efficiently reviewed within the timeframe proposed for this pilot.

And finally, the lead center must be CDRH. Our document control center or DCC processes the submissions that are received and performs an initial check of the eligibility criteria. If the 510(k) is found ineligible due to any of the criteria, the submitter will have to submit the 510(k) using the traditional method of submitting a valid e-Copy to the DCC. If the submitter attempts to submit a 510(k) using the eSubmitter application for a product that does not meet the eligibility criteria, it will be rejected for an invalid e-Copy.

It is important to note that when preparing a 510(k) for the Quik Review Pilot, there is no difference in the required content. The content expected for a Quik Review submission is the same as that for Traditional or Abbreviated 510(k). The only difference in preparing the 510(k) is that all the content is placed into the eSubmitter template. We still expect the exact same content as if you were submitting through the normal process.

Once constructed, the submission will be organized according to the lay out of the eSubmitter template. The order of the sections in the application is the order in which the submission will be formatted. This order cannot be rearranged.

The final package will contain both PDF attachments and XML file types. The FDA reviewer will only see the PDF attachments. The XML files are for the IT system to process the application upon receipt. Because this is an electronic submission, electronic signatures are used to sign documents such as the Truthful and Accurate statement.

The structure and questions in the eSubmitter templates compliment the structure and content in the smart template that FDA reviewers use to review your 510(k).

The eSubmitter template contains various icons to assist you in completing your submission. Some main icons to be aware of are:

The Expert View option. The button highlighted in the image to the right allows you to view the overall structure of the template and allows you to jump from section to section rather than filling out the template in the order presented. If you are familiar with Turbo Tax, the idea of Expert View mimics the same feature.

While in Expert View, folder icons allow you to see whether a page is complete or incomplete. If there is a question mark next to the folder, it means that page is incomplete. If there is a check mark, that page is complete. eSubmitter will only allow you to package the submission when all folders have a check mark.

The yellow light bulbs provide help text for what is expected for most of the questions. The blue dots indicate required questions. eSubmitter will not allow you to proceed without those questions answered.

A hard copy of the cover letter is needed in order to process the 510(k). This cover letter must contain the statement on this slide. If this statement is not included the submission may not be accepted into the Quik Review Program pilot.

For eligible Quik Review submissions, the parts of the eCopy guidance that describe the structure of a 510(k) will not apply.

Once your 510(k) is constructed, download only the generated ZIP file onto a CD, DVD or USB drive. Adding other items may cause a delay in processing your submission due to IT constraints. eSubmitter will not electronically submit your file. The

packaged submission must be physically mailed into the CDRH's DCC and must include a hard copy of the cover letter with the required statement. The DCC needs a hard copy to know what to process the submission as. For example, a 510(k), IDE, PMA or other submission type. It is also used to know where to route the submission and to get basic information for entry into the system. No valid eCopy is necessary for eligible submissions but they are still subject to MDUFA user fees.

There are three main differences in the review process. The first is that no RTA review is conducted for submission eligible for the Quik Review Pilot because eSubmitter will not construct a submission without all necessary sections provided. An RTA decision will be made in our system due to the IT structure and you will receive an email notice that the RTA has been waived. Please note that if sections are severely deficient preventing the review from proceeding and/or necessitating review staff to ask for substantial information, the file may be placed on hold.

Because these submissions are well organized and for well understood products, it is expected that this review will be conducted interactively without placing the file on hold. Both FDA review staff and industry are expected to interact quickly to resolve outstanding issues. These requests will be via email and will be followed up with a phone call by the FDA reviewer to ensure receipt of the request. Review staff have been instructed to leave a voice mail if there is no answer.

The final decision for Quik Review submissions should be rendered by FDA day 60.

In the event that an issue arises that cannot be handled interactively, FDA reviewers still have the option to place the file on hold to request additional

information. If the file is placed on hold you will receive an email notifying you that the submission will be converted to the traditional 90 FDA day timeline.

We anticipate that complex issues such as needing clinical data, the product being a combination product and the primary product code is outside the scope of the pilot as being the most common reasons for converting the submission. In order to convert the submission to a 90-day FDA timeline, the same process for converting a Special 510(k) is observed. The FDA reviewer must obtain concurrence from their management and it must then be presented to 510(k) staff for review and concurrence.

If you need to submit additional information via an amendment, you can use eSubmitter, you cannot use eSubmitter due to limitations with the software. Amendments must be submitted via the DCC and have a valid eCopy. If the 510(k) is found ineligible to continue through Quik Review, the FDA will email the official contact on the 510(k) to notify them why the submission was found ineligible and why it cannot be reviewed with 60 FDA days.

The 510(k) will then be reviewed according to the standard procedures using the 90 FDA day timeframe. If the file is placed on hold supplements must be submitted to DCC and must have a valid E-Copy. eSubmitter cannot be used for supplements or amendments.

As part of the pilot assessment, we will be collecting the following information, the total number of submissions received, the product code for those submissions, the 510(k) number, the total time to decision and if a submission is found ineligible to proceed through the Quik Review Program Pilot we will collect the reason why it was ineligible, the FDA day on which it was concurred upon as ineligible, and the FDA day it was placed on hold.

The Quik Review Program Pilot began on September 6, 2018. The pilot will run until we have collected enough data to determine the outcome of the pilot. We will notify the public when we believe we have reached that point. For the purpose of the pilot, we do not anticipate changes to the eligible product code list. However, we are happy to take suggestions of product codes to include should the pilot become policy and we will review those suggestions for appropriateness into the program.

We anticipate that this pilot program will result in shorter review times, better knowledge of the content required for a 510(k) submission, a standardized format that compliments FDA's review templates to allow for a more efficient review and elimination of the RTA review.

Here are some additional resources should you have additional questions following this Webinar. Thank you for your attention, this concludes the presentation, we are now happy to take questions.

((Crosstalk))

Coordinator: Thank you, we will now begin the Question and Answer Session, if you'd like to ask a question please press star 1 and record your name clearly. When your name is announced please state your company. Once again, to ask a question please press star followed by number 1. One moment please while we wait for the first question.

(Angela DeMarco): While we're waiting we do have a frequently asked question that we've been receiving, the question is that they recently submitted the 510(k) under the pilot using eSubmitter to construct the submission. After submitting it, they realized they attached incorrect information or checked an incorrect box,

and were wondering how to correct this? If you've already submitted the 510(k), you can email the lead reviewer for the submission, inform them of the error and change and then attach any documents to the email that were affected by that change.

Coordinator: Our first question comes from (Julia Brown) with Cotera, your line is open.

(Julia Brown): Hi there, we're about to submit a 510(k) with clinical data and do I understand correctly that any and all submissions with clinical data are ineligible?

(Angela DeMarco): So, we anticipate that clinical data could complicate the review so, we are encouraging that companies consider that before submitting clinical data with their Quik Review submission. Depending on the clinical data submitted, it is possible that it could proceed under the Quik Review, but we cannot say for certain that it would or would not. It depends on the actual data submitted.

(Julia Brown): Okay, but we could submit and see what happens? But they're not automatically ineligible I guess is what I'm asking. Is that correct?

(Angela DeMarco): Correct, yes, you can submit it and see what happens with the review team.

(Julia Brown): Okay, thank you.

Coordinator: Our next question comes from (Jennifer LaFleur) with Baxter Health Care, your line is open.

(Jennifer LaFleur): Hi, do you have to register to participate in the pilot?

(Angela DeMarco): There is no registration process that we have for this pilot, if you meet the eligibility criteria then you are eligible to submit under this program.

(Jennifer LaFleur): Okay, and I know you had a slide that showed the tool itself, do we just access that from the FDA Website, is there a link to that tool?

(Angela DeMarco): Yes, there is a link to that tool you can access it through the FDA Website. If you also go to the pilot page we have a link there as well.

(Jennifer LaFleur): Okay, and are you distributing these slides?

Irene Aihie: Yes, these slides are available at www.fda.gov/training/CDRH1.

(Jennifer LaFleur): Great, thank you, that's all of my questions.

Irene Aihie: You're very welcome.

Coordinator: Our next question comes from (Chris McClellan) with Phillips, your line is open.

(Chris McClellan): Hi, when you have enough data collected to make a decision on the pilot, does the pilot cease until it becomes policy or will it continue and then either a decision be issued that it's policy or not?

(Angela DeMarco): At this time, when we determine we have enough information to assess the pilot, we have not made a determination as to whether we will cease completely, any files that were already in house under the Quik Review Program will continue to be reviewed as such and that data may be added to the compilation.

(Chris McClellan): Okay, and I presume that the agency will advise if they do cease enrollment in the pilot?

(Angela DeMarco): Correct.

(Chris McClellan): Okay, and then if I may, I have an additional question, if Quik Review is found to be ineligible for Quik Review and converted to the 90-day timeline, does that immediately necessitate an additional submission or is it transitioned to the 90-day timeline with a request for any additional information that's needed?

(Angela DeMarco): It would transition into the 90-day timeframe without the need to submit a new 510(k).

(Chris McClellan): Okay, thank you, that's all my questions.

Coordinator: And as a reminder, if you'd like to ask a question please press star 1 and record your name and your company. Our next question comes from (William Chow), One Native, your line is open. Please un-mute your line.

(William Chow): Dr. (Martin) speaking on (William)'s behalf for Natives Medical, Inc., just real quick if I'm attempting and my device qualifies one of these eSubmitter 510(k)s, what kind of lead time will the staff there give industry when they plan to discontinue the pilot?

(Angela DeMarco): At this time, we will determine that and we will give enough advance notice so that anyone who still wanted to submit a Quik Review could still submit that 510(k). We will make that announcement with enough notice.

Dr. (Martin): Alright, thanks.

Coordinator: The next question comes from (Germain) with Striker, your line is open.

(Germain): Hi, my question is about the eligible product codes, we plan to submit a 510(k) under product code DQY for a product that has peripheral and neuro-vascular indications, however, in the information it says that the DQY code only applies for cardio-vascular and peripheral indications, since our product has peripheral and neuro-vascular would it still be applicable for the Quik Review?

(Angela DeMarco): So, currently the neuro-vascular indication for that product code are not included in this pilot due to concerns from the review group.

(Germain): Okay, thank you.

Coordinator: Our next question comes from (Rose) with AIP.

(Rose): Yes, does this have to be submitted through the ECTG format?

(Patrick Axtell): I think what you might be referring to is the ESG, the Electronic Submission Gateway and no, we're not using the Electronic Submission Gateway for this, you would just submit it as you do as an eCopy on a CD with a cover letter.

(Rose): Okay, great so, we would submit it the old way?

(Patrick Axtell): Correct, just like an eCopy but it would be a zip that you would be submitting.

(Rose): Okay great, because a lot of the things that are being submitted now have to be done all through that gateway platform. That helps a lot, thank you for taking my question.

(Patrick Axtell): Alright. One of the things we learned back in the 2014 pilot was that folks don't like the ESG so, we're not doing that this pilot.

((Crosstalk))

(Rose): Oh, thank you guys so much, yes, very tedious.

((Crosstalk))

Coordinator: Our next question comes from (Stephanie DelPayne) with Cook Research, Inc.

(Stephanie DelPayne): Yes, thank you for taking my question, I have two questions actually, where are the eligible product codes located? And the second is, it looks like combination products are not part of this pilot program but is there an expectation they will be part of the eSubmitter process?

(Angela DeMarco): So, to answer your first question, the list of product codes is on the pilot Webpage on FDA's Website for Quik Review. We have a pilot Web page that has the whole list of product codes. And for your second question, at this time we do not anticipate including combination products into this program. But it is a pilot now so it is possible that in the future it could be but, for purposes of this pilot, combination products are not included.

(Stephanie DelPayne): Thank you.

(Angela DeMarco): Yes.

Coordinator: Our next question comes from (David Robertson) with Med Tronic, your line is open.

(David Robertson): Hello, in the early slides there was a statement there or you had made the statement that the pilot program was available for traditional and abbreviated 510(k), later in the slide it said something regarding concurrence with a special 510(k), does that mean special 510(k)s are included in the pilot or not?

(Angela DeMarco): So, special 510(k)s are not included in the pilot. The reference to the special 510(k)s was for the concurrence process. We're keeping that concurrence process the same. If the Quik Review submission was to be converted to the 90-day timeframe, it would have to go through the lead reviewer's direct management and then also reviewed and concurred upon by 510(k) staff in order to be converted. We wanted to keep the two processes the same.

(David Robertson): Okay, thank you for the clarification.

(Angela DeMarco): Absolutely.

Coordinator: Our next question comes from (Kevin Daily) with Kevin Daily Consulting, LLC.

(Kevin Daily): Hi, if the submission is considered or found to be ineligible after submission, how quickly will the submitter know? How quickly with FDA inform the submitter that it has been rendered ineligible?

(Angela DeMarco): As soon as the ineligibility is identified and goes through the concurrence process we will notify the company.

(Kevin Daily): What timeframe would you expect that to be? Ten days, thirty days? That type of information is what I meant to ask.

(Angela DeMarco): It should be done within the first 30-days.

(Kevin Daily): Okay, thank you.

Coordinator: Our next question comes from (Valerie Simetry) with Ormco, your line is open.

(Valerie Simetry): Hi, I just wanted to confirm that no physical hard copy is required, it's just basically the CD and the letter, is that correct?

(Angela DeMarco): Yes, the only hard copy that we require is the copy of the cover letter.

(Valerie Simetry): Okay, very good. And then I know you mentioned that you would give notice to industry if the pilot is discontinued, but is it expected that it will run through the end of the year?

(Angela DeMarco): Yes.

(Valerie Simetry): Okay, thank you.

Coordinator: Our next question comes from (Elizabeth Fitzgerald) with Night Submission, your line is open.

(Elizabeth Fitzgerald): Hi, thank you for taking my question. My question is how do you plan to work with industry as industry develops complimentary offering and publishing tool?

(Angela DeMarco): Could you clarify the question with the – we're not entirely sure what you mean?

(Elizabeth Fitzgerald): Sure, it seems like there are some natural synergies between, you know, a software that could assemble a 510(k) submission and the software like the eSubmitter program and wondering if you have any plans to sort of work with industry to develop tools like that?

(Patrick Axtell): Not right now - we don't have any plans for that right now.

(Elizabeth Fitzgerald): Alright, thank you.

Coordinator: Our next question comes from (Patricia Leyman) with AMU Corp, your line is open.

(Patricia Leyman): Hi, thanks for taking my call, I think my question has been partially answered already. I was just wondering how long the agency is planning to run the pilot for. And if there's any indication that if the pilot is successful that the agency plans to increase the number of product codes?

(Angela DeMarco): So, we intend to run the pilot until we've collected enough data to determine the outcome. We will give advance notice when we believe that we have reached that point for those that were still anticipating submitting through the Quik Review Pilot. As for the product code list, we are happy to take suggestions for new product codes to add to the list and we will review those suggestions and see whether or not they are actually appropriate for this pilot – or for the program if it becomes official policy.

(Patricia Leyman): So, is the expectation to run for at least the next three to six months or is it going to be longer than that to determine?

(Angela DeMarco): We believe it will run for at least three to six months so that we can collect enough submissions through the pilot.

(Patricia Leyman): Okay, thank you.

Coordinator: As a reminder, to ask a question please press star followed by number 1. Our next question comes from (Veronica Meredith) with TE Health Care.

(Veronica Meredith): Yes, I'd like to ask we put in a submission about three weeks ago and you had mentioned that in the FAQs that there would be a reviewer assigned, if you haven't heard that there's a reviewer assigned is it progressing through the process?

(Angela DeMarco): If you're having difficulty with your specific submission, please contact the 510(k) program and we will be happy to look into the issue for you.

(Veronica Meredith): Okay, I just didn't know if there was a notification of assigning a reviewer or, you know, because it skips the RTA kind of.

(Angela DeMarco): Yes, so, you should still receive an email notification because the reviewer still needs to input an RTA decision, so, you should still be receiving a notice that the RTA was waived and it should include the name of the lead reviewer, but please follow up afterwards with the 510(k) program staff and we will be happy to assist.

(Veronica Meredith): Okay, thank you.

Coordinator: Our next question comes from (Brian Pender) with Welch Allen, your line is open.

(Brian Pender): Alright, this is (Brian), I think my question was already answered. I just wanted an estimate as far as how long the pilot would be running for and you had answered, you estimated three to six months so, yes, that answered my question.

(Angela DeMarco): Okay, yes.

(Brian Pender): Thanks.

Irene Aihie: We'll take our next question.

Coordinator: Our next question comes from (Sue Lap) with Lap Medical Consulting, your line is open.

(Sue Lap): Thank you, my question is if a company has a current 510(k) going through the process, and they have some major deficiencies which requires some additional testing which really pushes the timeline and they chose to withdraw, adjust the testing, get the results back, and then compile, you know, get that information once it's withdrawn, would that qualify for the Quik Start Program resubmission?

(Angela DeMarco): So, if you meet the eligibility criteria of the Quik Review Program Pilot, then you're more than welcome to submit under the pilot program.

(Sue Lap): Would we have to then, you know, add additional details about the deficiencies being answered, would a letter of clarification on those deficiencies highlighting what we've done, you know, the company doing that, would that have to be part of, you know, should we add that in and then submit it in the Quik Start Program?

(Angela DeMarco): So, as with other 510(k)s, should there have been a prior submission, if there were any outstanding deficiencies we do expect those deficiencies to be addressed in the new submission.

(Sue Lap): Okay.

(Angela DeMarco): That content requirement wouldn't change.

(Patrick Axtell): And there is a part in the eSubmitter template called Related Submissions which is where you would upload any attachments and provide that information.

(Sue Lap): Okay, and that's called related submissions?

(Patrick Axtell): Correct, it's like maybe the fifth page in on the eSubmitter template.

(Sue Lap): Okay, thank you so much, I appreciate it.

(Angela DeMarco): You're welcome.

Coordinator: Our next question comes from (Alison Comeano) with Regulatory Strategy, your line is open.

(Alison Comeano): Hi, thanks for taking my call or my question, so, I have a question about the guidelines for interactive review, are there any shared goals with that? I know that reviewers' sort of set the tone with how fast they want feedback, is there any goal about, you know, whether or not they're going to give you more than 24-hours or 5-hours to respond to things? And then also, follow up question to that, if you can't respond in that timeframe, you know, I know you

can ask for an extension but if you also feel like you can't answer those questions within the first 60 days, or in that 60 day window, is it possible to ask for your file to get converted to the 90 day and be placed on hold?

(Angela DeMarco): Yes so, for any interactive requests the lead reviewer will make an assessment of how long they believe the response could take, if you need more time on that please contact the lead reviewer as soon as possible, they're very happy to work with you on adjusting the timeframe should it be needed. And as for requesting conversion to a 90 day, if you believe that you would like the hold and need the extra time in order to complete the request, please let the reviewer know and we will take that into consideration.

(Alison Comeano): So, is it possible though if you can't answer your questions in that timeframe that they could still make the decision by day 60 as an NSE or would it be more likely that they would then covert it to the 90-day process?

(Angela DeMarco): That would depend on the type of question being asked and extenuating circumstances around the issue.

(Alison Comeano): Okay, thank you very much.

(Marjorie Shulman): And this is (Marjorie Shulman), I just wanted to add something to that, remember the 60 days is the FDA time but we're not placing these on hold. So, we can't give the company 60 days to respond because the file is not stopping. So, it is going to be a negotiation with the reviewer and if it's more than probably like five to seven days or something then that's probably going to be a reason for conversion.

(Alison Comeano): Okay, thank you, that's helpful.

Coordinator: Our next question comes from (Julia Brown) with Cotera, you line is open.

(Julia Brown): Hi, sorry, I had a follow up question to my earlier question regarding clinical data, normally when we submit clinical data we submit an Excel spreadsheet but the slides or the presentation stated that you only have PDF in the submissions, so, does that mean that we would need to convert the Excel spreadsheet to PDF or does some – does the eSubmitter magically do that?

(Patrick Axtell): No, it doesn't magically do that.

((Crosstalk))

(Patrick Axtell): You've got two options so, you could convert that Excel to a PDF or there is maybe on the second to last page of the template asks for any other types of documentation and that's where you would upload – you could take that Excel file or any other file and make it a zip and then you would attach that .zip. So, the eSubmitter template accepts PDF throughout and then on the last page it will accept .Zips which contains any other types of images and so on.

(Julia Brown): Okay, so, like the current eSubmitter, I thought maybe the Quik one was less forgiving.

((Crosstalk))

(Patrick Axtell): No, works the same way and that's within – it's consistent with how we do eCopy as well where we're accepting PDF but also you can put these .zip files in the miscellaneous files folder and that's how you get, you know, video files in as in eCopy, it works the same way.

(Julia Brown): Okay, awesome, thanks, that really is the end of my questions, thanks.

Irene Aihie: We'll take our next question.

Coordinator: Next question comes from (Brent Navelett) with (Navelett Ruling), your line is open.

(Brent Navelett): Yes, hi, thanks for taking questions, I believe you mentioned that anywhere signatures are needed that electronic signatures are going to be used, is there a separate process for establishing electronic signatures or is that built into the use?

(Patrick Axtell): At the very end of the template, when you're about to package it, there's a place where you're going to upload your electronic signature PDF file and there's some directions there. If you click on the yellow light bulb, there are directions on how to acquire electronic signature that's usable by the eSubmitter template. And that signature would get used on certain documentation such as the truthful and accurate statement. If you're not a representative of the applicant, then there is an option in the eSubmitter template for you to attach a truthful and accurate statement that has a physically signed out cover letter, or physically signed out signature. So, you have those two options in the eSubmitter template.

(Brent Navelett): Okay, great, thank you.

Coordinator: Our next question comes from (Katzy Fabla) with FIFE.

(Katzy Fabla): Yes, hello, I have one question, in your slide you showed that if the device or the leading device has a primary code included in the program, what about if the leading device is within the program and within the submission there are accessories which has a different product code not listed in the list, is this

510(k) still included in the program or is it dropped and goes back to the traditional?

(Angela DeMarco): So, if the primary product code is on the list it will be accepted into the Quik Review Program. If there are secondary product codes, we are not specifically excluding any secondary product codes, you are allowed to have secondary product codes. Please be aware though that depending on the secondary product code if it adds too much complication to the file then we may have to convert it to the 90-day timeframe but we are not specifically excluding the inclusion of secondary product codes.

(Katzy Fabla): Okay, thanks.

Coordinator: Once again, to ask a question please press star followed by number 1, record your name and your company. Our next question comes from (Video) with Athena Medical, your line is open.

(Video): Hi, thank you for taking my question, I just had the same question before this question, I do have a secondary product code question, and you said if there are too much complications in the file, so, could you just give some examples like does it depend on how complicated the product code is or if it's a simple product code will it accept it?

(Angela DeMarco): So, it would depend on the product code itself and what it added to the submission. So, if it added technological characteristics or indications for use that required more data or like clinical data, if it required additional information that could potentially complicate the review then the review team would reach out to you and inform you of this.

(Video): Okay, thank you.

Irene Aihie: We'll take our next question.

Coordinator: Our next question comes from (Nibby) with Parametal Medical Imaging, your line is open.

(Nibby): Hello, thank you for taking my question, (Nibby) here, I was wondering what the idea rationality behind the selection of eligible codes?

(Angela DeMarco): Our product codes were selected by the review groups as being devices that they believed were well established and well understood and would be able to reasonably conduct a review within the 60-day timeframe.

(Nibby): Okay, so, it was not necessarily associated with like an assessment of the product or indications used but more to do with the general experience with those codes?

(Angela DeMarco): It's somewhat of a mix of the general experience with the product code and the risk area because 510(k) devices are moderate risk devices. There is a range of risk within that. However, for the purposes of the pilot they were determining the product codes based on experience with the submission and the devices rather so that they could see that these devices would be reasonably reviewed within the 60-days due to their experience and knowledge of the device.

(Nibby): Okay, so, if there is a device, I'm sorry, I do have a follow up question, so, if you have a device that's been cleared, you've got like one or two generations of the device but the product code hasn't been recognized, that's something that will – that could be addressed only once and if this becomes a policy.

There is no reason for industry to believe that there could be a revision to the list sooner, is my understanding correct?

(Angela DeMarco): So, for the pilot we don't anticipate making any changes however, based on the assessment, changes to the list could be made.

(Nibby): Okay, thank you so much.

Coordinator: Our last question comes from (Nana Carame) with Merritt Medical, your line is open.

(Shonsla): Yes, hi, this is (Shonsla) here, I have a question.

Irene Aihie: I'm sorry, can you please speak up, it's difficult for us to hear you.

(Shonsla): Can you hear me okay now?

Irene Aihie: Go forward with your question.

(Shonsla): Okay, (unintelligible) for submitting in laser devices and in that situation one had to establish some kind of a link where this information would have come from, the FDA site and I'm wondering if this link that you're saying is just get go thing or still that requires that kind of sort of test and information that you would receive before you would start that process because I'm wondering if I just hold this link on the day I'm trying to submit and I find that oh, I need to go through some kind of information process, so, just want to get that clarification.

(Patrick Axtell): I think what you're referring to is the Electronic Submission Gateway, that whole process provides test submissions and you go through this multi-step

process of getting an account set up through Web trader for that, and you don't have to do that for this, if that is what you're referring to.

(Shonsla): Okay, thank you alright, so we just open the link and the system and nothing else ahead of time is required for this.

(Patrick Axtell): No, you wouldn't have to submit anything ahead of time, right, so the way that this would work is you would download the eSubmitter application for our Website, you choose the proper template in there, you answer all the questions, you package that .zip at the end and then you would submit that to us and there's nothing you have to do before. And that's basically the process right there.

(Shonsla): Okay, nothing ahead of time?

(Patrick Axtell): No.

(Shonsla): Alright, thank you.

Coordinator: At this time, we have no further questions, I would like to turn the call back over to Irene Aihie.

Irene Aihie: Thank you, this is Irene Aihie, we appreciate your participation and thoughtful questions. Today's presentation and transcript will be made available on the CDRH learn Webpage at www.fda.gov/training/cdrhlearn on Thursday, October 18th. If you have additional questions about today's presentation please use the contact information provided at the end of the slide presentation. As always, we appreciate your feedback. Following the conclusion of the Webinar please take a short eighteen question survey about your FDA CDRH Webinar experience. This survey can be found at

www.fda.gov/cdrhwebinar immediately following the conclusion of today's Webinar.

Again, thank you for participating and this concludes today's Webinar.

Coordinator: Thank you for your participation at today's conference, please disconnect at this time.

END