FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

Welcome to today's FDA/CDRH Webinar

Thank you for your patience while additional time is provided for participants to join the call.

If you have not connected to the audio portion of the webinar, please do so now:

Dial: 1-888-989-4719**; International:** 1-630-395-0022

Passcode: 6679159

Quality in 510(k) (“Quik”) Review Program Pilot

Angela DeMarco
Biomedical Engineer
510(k) Staff
Office of Device Evaluation

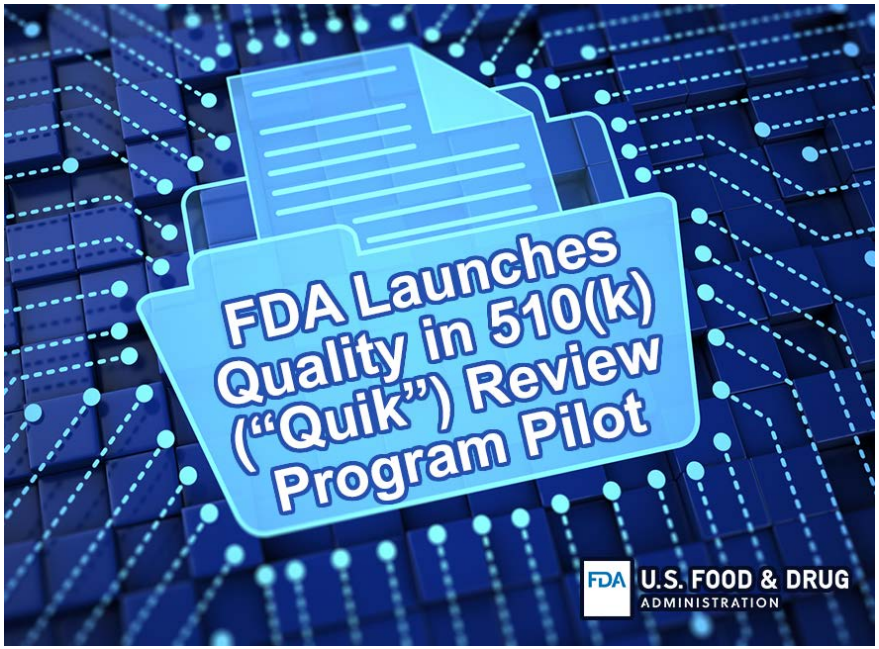
Patrick Axtell
Biomedical Engineer
Office of Device Evaluation

Center for Devices and Radiological Health

Agenda

This presentation will cover:

- Purpose of the Quik Review Program pilot
- Background on Program development
- Changes compared to the current 510(k) process



Objectives

After this training, you should know:

- How to determine eligibility for the Quik Review Program pilot
- How to prepare your 510(k) for the Quik Review Program pilot using the FDA's eSubmitter template
- What to expect from the review process

Purpose of the Quik Review Program pilot

The purpose of the Quik Review Program Pilot is to:

- simplify how manufacturers of certain moderate risk medical devices complete a premarket notification (510(k)) submission, and
- evaluate whether use of the FDA's free eSubmitter software will result in well-organized submissions that can be reviewed more efficiently.

Background

- The FDA periodically pilots programs to help improve consistency and efficiency in 510(k) review, and help reduce total time to decision.

- The Center for Devices and Radiologic Health identified certain products they believe can be reviewed more efficiently than the Traditional 510(k) Pathway.

- The eSubmitter software was updated based on experience from the 2014 eSubmitter pilot.

Definitions

- **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 www.fda.gov. The software formats, packages, and validates the submission, but does not submit it.
- An **eSubmitter template** is a template located within the eSubmitter application. It is used to construct the submission.

Scope

- Traditional or Abbreviated 510(k)s that meet the eligibility criteria of the Program

- This pilot **does not** include:
  - Special 510(k)s
  - In-vitro Diagnostics
  - Biologic products

Eligibility Criteria

A 510(k) must meet <u>all</u> the following criteria to be eligible:

1. The primary product code is on the pre-identified list of product codes
2. The submission was constructed with the eSubmitter template "CDRH: Non-In Vitro Diagnostic Device – 510(k)"
3. The product is not a combination product (for example, drug-device or biologic-device combination)
4. The lead Center for the device is the FDA's Center for Devices and Radiological Health (CDRH)

If found ineligible, the submission will be subject to eCopy requirements.

Preparing the 510(k)

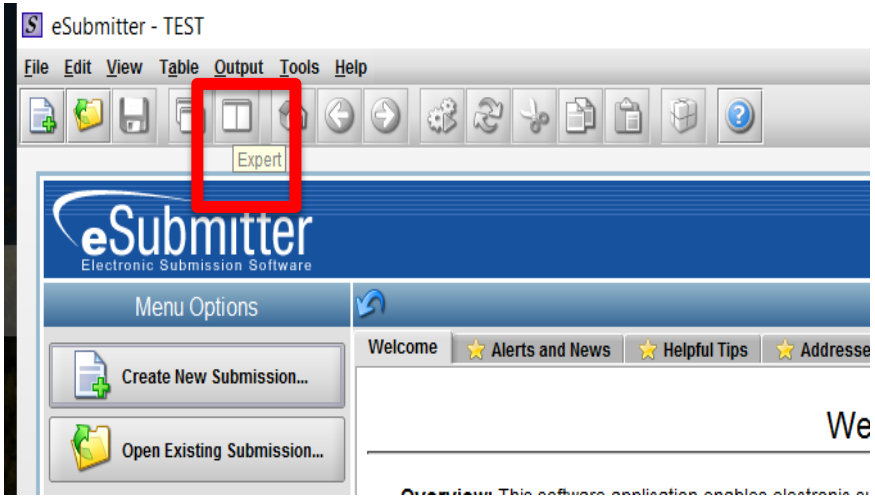
No difference in required content

Use the eSubmitter template entitled "CDRH: Non-In Vitro Diagnostic Device – 510(k)"

- Organized according to the layout of the template
- Final package contains PDF attachments and XML file types
  - XML files are used to process the application and will not be seen by FDA reviewers
- Electronic signatures are used in the submission (for example, on the Truthful and Accurate statement), rather than physical signatures
- Structure and questions complement the smart template

Preparing the 510(k)

eSubmitter Template Icons



- **Expert View:** Select the Expert button in the top left of the eSubmitter application to view the structure of the template

- **Folder icon:** In Expert view, you can see whether a page is complete or incomplete by the presence of a check mark or question mark on each folder, respectively. eSubmitter will only allow you to package a submission when all folders have a check mark.

- **Yellow light bulbs:** Provide help text for most questions in the eSubmitter template

- **Blue dots:** Questions with a blue dot are required

Preparing the 510(k)

Additional Items

- The cover letter **must** contain the following statement:

  "This submission is part of the Quik Review Program Pilot, and is organized according to the standard eSubmitter output package. Accordingly, special eCopy processing applies. As per the agreement for the Quik Review Program Pilot, no full paper copies are required."
- The parts of the eCopy guidance that describe the structure of a 510(k) submission will not apply to the Quik Review Program Pilot

Submitting the 510(k)

- Once constructed through eSubmitter, download **ONLY** the ZIP file onto a CD, DVD, or USB drive.
  - Additional items on the CD, DVD, or USB drive may cause a delay in processing your submission
- Send by mail to CDRH's Document Control Center
- Include a hard copy cover letter with the required statement
- No valid eCopy necessary
- Applicable MDUFA User Fees

Differences in Review

Main differences in the review process:

- No “refuse to accept” review
  - eSubmitter will not construct the submission without all necessary sections provided
  - Email notice that the “refuse to accept” is waived
- Interactive review
  - Email requests for additional information, followed up by phone
- FDA will make its final decision by day 60

Differences in Review

Items to note in the review process:

- Hold to request additional information is still available
- If placed on hold, the submission will be converted to the 90 FDA Day timeline. Some examples of reasons for a hold include, but are not limited to:
  - Complex issues (such as clinical data, need for additional testing)
  - Combination product
  - Primary product code outside the scope of the pilot
- Same concurrence process as converting a Special 510(k)
- Amendments cannot be submitted using eSubmitter.

If Found Ineligible

- The FDA will email the official contact of the 510(k) to:
  - State the reason for ineligibility
  - Explain why a review cannot be completed within 60 FDA days
- The 510(k) will be reviewed according to standard procedures using the traditional 90 FDA day timeframe.
- If placed on hold, eSubmitter cannot be used to submit a supplement.

Pilot Assessment

The FDA will collect the following:

- Total number of submissions received
- Product code
- 510(k) number
- Total Time to Decision
- If a submission was found ineligible
  - The reason
  - The FDA Day on which it was concurred upon as ineligible
  - The FDA Day it was placed on hold

Stakeholder Considerations

- The pilot began September 6, 2018
- We do not expect changes to the list of product codes, but are open to suggestions in the event this pilot becomes official policy
  - Suggestions can be sent to 510k_Program@fda.hhs.gov

Benefits

- Shorter review times
- Knowledge upfront of what is expected in a 510(k) submission
- Standardized format that complements the reviewer's smart template promoting a more efficient review
- No "refuse to accept" review

Resources

- 510(k) Program Pilot webpage https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm618561.htm
- FDA eSubmitter webpage: https://www.fda.gov/ForIndustry/FDAeSubmitter/default.htm
- Program Email Address

  510k_Program@fda.hhs.gov
- Questions about the eSubmitter application esubmitter@fda.hhs.gov
- If you find malfunctions or errors, or have feedback on the eSubmitter templates eSubPilot@fda.hhs.gov

Questions?

Division of Industry and Consumer Education:
DICE@fda.hhs.gov

Slide Presentation, Transcript and Webinar Recording will be available at:

http://www.fda.gov/training/cdrhlearn

Under Heading:
How to Study and Market Your Device

Please complete a short survey about your FDA CDRH webinar experience. The survey can be found at www.fda.gov/CDRHWebinar immediately following the conclusion of the live webinar.