Frequently Asked Questions Submitted by the Audience

I’d like to learn more about electronic submissions: what do we need; are there any differences in cost; any differences in the information provided; once submitted by electonics, can we go back to paper?

FDA Response

- The FDA eSubmitter is free.

  It is a downloadable application a company can use to submit electronic 510k submissions to CDRH.

  For general information on FDA eSubmitter:

  http://www.fda.gov/ForIndustry/FDAeSubmitter/default.htm

FDA Response

- For information specific to OIVD:

  http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107776.htm.

The FDA eSubmitter allows for complete electronic submission of a 510k.

At this time, only 510k submissions sent to OIVD can be submitted electronically.

FDA Response

- There is no additional cost for submitting electronically
- There is no difference in the information requested when submitting electronically.
- Electronic submissions are not mandatory, so you may revert back to responding via paper if you initially submitted electronically. We prefer that you continue to submit electronically.

FDA Response

- CDRH also offers the eCopy program
- The eCopy program allows a sponsor to send an electronic copy of the 510k submission on a CD along with a paper copy. This program is not limited to OIVD.
- Visit: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm

Frequently Asked Questions Submitted by the Audience

- I’d like to ask about the current policies for putting 510k’s on phone hold. Is there anything in writing? Does the phone hold “reset” the review clock?

FDA Response

- Telephone holds are generally followed up with an email. A formal letter is not sent by OIVD, but a letter is sent from the Center.
- A telephone hold technically resets the review clock, but to meet MDUFMA goals of 90 days total review time, a telephone hold actually just stops the review clock.
- A telephone call may result in a desk hold where the review clock is not stopped.

Frequently Asked Question Submitted by the Audience

- We received a series of questions about codevelopment and companion diagnostics.

FDA Response

- The Agency intends address questions about codevelopment and companion diagnostics within the planned codevelopment guidance.

Frequently asked Question Submitted by the Audience

- Under the 510k substantial equivalency paradigm where a firm is comparing to a legally marketed predicate is it appropriate and within the scope of the OIVD review branch to compare the performance of the candidate device to the performance of a second legally marketed device not selected as the predicate by the firm?

FDA Response

- Yes. In cases where there is a legal predicate named by the sponsor, but this predicate is no longer marketed due to significant advances in science and technology, or where FDA has acknowledged a review error and has required subsequent devices of the same type to have corrected specific performance characteristics, it is reasonable for a reviewer to request comparison to a different, more relevant predicate, if this will provide necessary safety and effectiveness benefits.