Checklists and Guidance from FDA on the Acceptance Criteria for 510(k) Submissions

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FDA recently issued a final guidance on the Refuse to Accept Policy for 510(k)s[1] (Guidance). The Guidance outlines the procedures and criteria FDA uses to determine whether a medical device premarket notification (510(k)) submission is administratively complete and should be accepted for substantive review. The criteria for traditional, special, and abbreviated 510(k) submissions are covered by the Guidance. The Guidance also includes, as appendices, the Acceptable Checklists FDA will use to evaluate all 510(k) types.

Background

The Guidance focuses on the criteria used for acceptance review, during which the 510(k) is assessed for administrative completeness, rather than substantive review. FDA first reviews a submission against specific acceptance criteria and will inform the submitter within 15 calendar days of receipt if the submission is administratively complete. If the submission is not administratively complete, FDA will issue a refuse to accept (RTA) to the submitter. The Guidance does not affect the substantial equivalence decision-making process that occurs after the 510(k) is accepted for review, but it does establish the beginning of the review period. The review clock for submissions that are accepted during the initial acceptance review (within 15 calendar days of receipt) starts with the date of receipt. For 510(k) submissions received in Fiscal Year 2018, the average Total Time to Decision goal for FDA and industry is 124 calendar days.[2]

The Guidance provides seven preliminary questions that are used in the initial screening of a 510(k) submission:

1. Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)?
2. Is the submission with the appropriate Center?
3. If the device or combination product with a device component was assigned to CDRH after a Request for Designation (RFD) was submitted, is the product the same (e.g., design, formulation) with the same indications as that presented in the RFD submission?
4. Is the submission for a combination product that contains as a constituent part an approved drug that is under exclusive marketing rights? (503(g)(5))
5. Is this device type eligible for a 510(k) submission?
6. Is there a pending PMA for the same device with the same indications for use?
7. If clinical studies have been submitted, is the submitter the subject of the Application Integrity Policy (AIP)?

FDA will review 510(k) submissions in accordance with the relevant Acceptance Checklist, and will also determine whether the submitter provided a justification for any alternative approach that does not correspond with the checklist.

If the 510(k) is not accepted, FDA will issue a RTA and will include a copy of the checklist that indicates which items FDA considers to be missing. If the submitter wants to resubmit the 510(k), it is typically sufficient to only submit the missing portions of the submission that were identified in the

1 https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm315014.pdf
2 https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf

checklist. The entire 510(k) usually does not need to be resubmitted unless FDA indicates otherwise.

AGG Observations

1. The final Guidance was originally issued in 2013; the updated 2018 Guidance incorporates certain combination product innovation requirements of the 21st Century Cures Act.[3] One of the 21st Century Cures requirements is that submissions for device-led drug-device combination products must include the appropriate patent statement or certification. We will not elaborate on the details of patent statements and certifications, but note that this requirement has been incorporated into the RTA checklists. A submitter of a 510(k) that is not a device-led combination product should note "N/A" for this element of the checklist.
2. The Guidance and checklists are not intended to take the place of detailed descriptions of the substantive information a 510(k) needs to include. More detailed descriptions of the requirements are set forth in the regulations at 21 CFR part 807.
3. 510(k) submitters should keep in mind that the notification of the result of the acceptance review will only be sent to the designated contact person identified in the submission. Should the contact person change, the submitter should be sure to update the file.

3 21 U.S.C. §353(g)

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