# A Little Help from Our Friends: FDA Issues a Final Guidance Document on the 510(k) Third Party Review Program (3P510k)

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On March 12, 2020, the Food and Drug Administration issued a final guidance on its Third Party (3P510k) Review Program titled, *Guidance for Industry, Food and Drug Administration Staff and Third Party Review Organizations*.[1] Under the 3P510k Review Program, FDA recognizes certain third parties (3P510k Review Organizations) to review premarket notification submissions (510(k) submissions) for low to moderate risk and less complex medical devices and to recommend a device classification. The 3P510k Review Program also serves as a voluntary alternative review process so that manufacturers of eligible devices (to be discussed) have an avenue to seek a more rapid 510(k) review decision.

The purpose of the recently-issued guidance document is to outline FDA's current thinking on key aspects of the 3P510k Review Program to help avoid the routine re-review of 510(k) submissions already reviewed by a 3P510k Review Organization. The guidance covers the following:

- FDA's expectations for 3P510k Review Organization review of submissions
- Factors used to establish device type eligibility for the program
- Requirements and recommendations for recognition and re-recognition as a 3P510k Review Organization
- The content and format of a 3P510k Review Organization's application for recognition and re-recognition in the program
- The process for suspension or withdrawal of an organization's participation in the program

The guidance also covers FDA's current thinking on leveraging the International Medical Device Regulators Forum's (IMDRF's) requirements for Regulatory Reviewers under the Good Regulatory Review Practice (GRRP) and the Medical Device Single Audit Program (MDSAP), as appropriate. We provide a high-level overview of the guidance document below. We will not discuss every topic included in the guidance.

## Background

Under the 3P510k Review Program, 3P510k Review Organizations review 510(k) submissions for certain medical devices. FDA considers a number of factors, which are discussed more fully below, when determining which device types are eligible for the 3P510k Review Program. After the 3P510k Review Organization completes its review, it sends the 510(k) submission and the 3P510k review documentation generated by the review organization to FDA. Upon receipt, FDA conducts its own review and makes a final decision on the submission. According to the Federal Food, Drug, and Cosmetic Act, FDA is required to make a determination regarding the initial classification within 30 calendar days after receiving a recommendation from a review organization.

1 The guidance document is available at the following https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-third-party-review-program. The guidance document supersedes other FDA guidance documents, including "Implementation of Third Party Programs Under the FDA Modernization Act of 1997; Final Guidance for Staff, Industry, and Third Parties" issued on February 2, 2001, and "Guidance for Third Parties and FDA Staff; Third Party Review of Premarket Notifications" issued on September 28, 2004.

## Factors Used to Determine Device Type Eligibility

FDA will consider the following factors in determining device type eligibility for the 3P510k Review Program:

- The risk of the device type, or subset of such device type
- Whether the device type, or subset of such device type, is intended to be permanently implanted in the body or to sustain or support human life
    - A review organization seeking recognition to review such devices must provide a detailed public health justification explaining why the device type should be eligible for review and how this will positively affect public health
- The extent to which the device type is well understood
- The extent to which necessary information to make a well-informed recommendation is available to 3P510k Review Organizations
    - If information materially relevant to evaluating device type is not able to be shared outside the agency, the device type may be ineligible for review under the program
- The extent to which the review of the device type does not require multifaceted, interdisciplinary expertise
- The availability of post-market data suggesting that the device type is the subject of safety signals

If a device type is considered eligible for the review program, but a proposed modification for a specific submission raises different concerns related to the factors above, that submission may be determined to be ineligible for 3P510k review.

## Review of 510(k) Submissions by 3P510k Review Organizations

According to FDA, 3P510k Review Organizations should conduct "FDA-equivalent" reviews of devices. FDA expects review organizations to conduct their review in accordance with the key steps described in the guidance document (e.g., conduct and document substantive review) and in accordance with their own quality control practices. Before reviewing a submission, 3P510k Review Organizations are instructed to determine whether the organization has the expertise to review the device type and whether the device type is eligible for 3P510k review based on the product code classification database or FDA's Third Party Review public website. If the review organization submits a 510(k) submission for an ineligible device (or for a device the organization is not qualified to review), FDA will place the submission on hold and notify the organization of its assessment.

Review organization should also ensure that:

- Submissions are administratively complete and conduct an acceptance review of the 510(k) submission based on applicable regulations to assess whether the 510(k) submission includes all required information
- Identify at least one Final Reviewer who is independent from prior review of the submission and who is responsible for providing a final supervisory assessment before it is submitted to FDA
- Identify any deficiencies during their review and contact the 510(k) submitter regarding the deficiencies
    - Document the deficiencies, the submitter's response to the deficiencies, and the discussion on the adequacy of the response in the review memorandum sent to FDA
- Once the review organization has made a final recommendation, it should prepare the review documentation specifying the reasoning and steps that led to the final recommendation
- Upon submission of the recommendation, FDA will begin to review the documentation, and if necessary, the 510(k) submission
    - If FDA determines that additional information is needed to make a substantial equivalence determination, it will contact the review organization by telephone or email
- The guidance document also includes a section regarding the dispute resolution protocol for when a 510(k) submitter disagrees with an FDA decision or action, including an email address for 510(k) submitters to submit a complaint against a 3P510k Review Organization

The guidance puts review organizations on notice that, if additional requirements are announced in the Federal Register, the review organization must meet them.

## AGG Observations

- 510(k) submitters interested in pursuing the 3P510k Review Program should carefully review FDA's guidance document and determine whether their particular device is of the type that can be reviewed under the program.
- A device manufacturer should also consider whether using a Third Party Review Organization could significantly help reduce the amount of time from submission to clearance for their device. As noted previously, FDA is required to make a determination regarding the initial classification within 30 calendar days after receiving a recommendation from a review organization.
- 3P510k Review Organizations need to make sure that they are carefully following all of FDA's guidance in order to remain eligible to participate in the program.
- The guidance document signifies the agency's continued attempt to focus its review on more complex and higher risk medical devices.

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