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December 13, 2018

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: ***Docket No. FDA-2016-D-2565***

Dear Sir/Madam:

The Advanced Medical Technology Association (AdvaMed) provides these comments in response to a request regarding the Food and Drug Administration (FDA or "Agency") Center for Devices and Radiological Health draft guidance *"510(k) Third Party Review Program."* Notice of this draft guidance and request for comments were published in Federal Register Vol. 83, No. 179/Friday, September 14, 2018.

AdvaMed is the world's largest association representing manufacturers of medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. Our members range from the largest to the smallest medical technology innovators and companies. We welcome the opportunity to comment on this guidance and look forward to working with FDA to ensure the revised guidance meets the needs and expectations of both FDA and industry.

AdvaMed strongly supports the proposed FDA actions to reduce, and ultimately eliminate, the substantive re-review of 510(k) submissions reviewed by Third Party Review Organizations (3PRO or 3P). This plan ensures that the device types eligible for 3P review are appropriate; gives 3PRO reviewers the tools they need to perform appropriately; provides a way for 3PROs to demonstrate they can apply FDA's criteria for reviewing 510(k) submission packages; implements a framework for FDA processing of 3PRO 510(k) submission packages; and uses appropriate measures to monitor and improve the 3P Review Program. Successfully implementing these actions should allow FDA to focus resources on higher risk and complex devices; spend less time on routine re-review; enhance time to market for lower risk and less complex devices; and maintain confidence in safety and effectiveness of lower risk and less complex devices.

AdvaMed appreciates FDA efforts to define the revised third party review program and to provide detailed requirements for third party organizations in the draft guidance. AdvaMed has a few suggestions for clarifying certain parts of the guidance including a recommendation to more specifically stating the goal of eliminating the need for re-review of a 510(k) that has been reviewed by a 3PRO.

Sincerely,

/s/

Ruey C. Dempsey
Vice President, Technology & Regulatory Affairs

ADVAMED COMMENTS

510(k) Third Party Review Program

Draft Guidance for Industry, Food and Drug Administration Staff, and Third Party Review Organizations

Line(s) No. – Line number of the guidance

Change – Proposed Change to the guidance.

Reason – Reason/Rationale for the proposed Change.

Line(s) No.	Change	Reason
General	FDA has stated that one of the goals of this draft guidance is to eliminate the re-review of the 510(k)s reviewed by third parties. That goal is not clearly stated.	The guidance provides information on the certification and management of third party review organizations. Implementing these requirements will ensure that FDA can trust the work of third party reviewers. Therefore, there will be no need for routine re-review of 510(k).
130	Add the following: …FDARA and thereby eliminate the need for routine review by FDA of 510(k) submissions which have been reviewed by a 3P.	Clearly state that reviews by qualified, trusted third parties should eliminate the need for using valuable FDA resources to re-review 510(k) submissions.
335	Further define the “different organizational components.”	It is unclear which organization is being discussed. Is it FDA? Or the 3P? Or the submitter? This scenario needs to be more clearly defined.

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510(k) Third Party Review Program

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Line(s) No.	Change	Reason
347-349	Clarify if companion diagnostics are eligible for third party review.	Although the description of eligibility requirements is very comprehensive, the uniqueness of some aspects of companion diagnostics make it difficult to make an appropriate decision.
366	List the frequency of future updates.	It will be helpful to understand how often FDA will update the list. Will it be updated immediately after a device type is determined eligible?
390	Provide information on when the FDA determination clock starts.	It will be helpful to know when the 30-day clock begins on the FDA determination process. Is it after the submission from the third party is found to be acceptable/eligible?
418	Add the word "issued" so sentence reads: "…review FDA's guidance database to obtain any relevant final guidance documents…"	Draft guidance documents may change, and companies should not be judged by draft documents.
471	Add: "Specifically, a consultation by the 3P and FDA, as needed, is held prior to beginning the review of the 510(k) by the 3P and a consultation is held in the early stages of the substantive review."	Wording in this section is not clear.

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Line(s) No.	Change	Reason
475	Provide examples of the topics that could be discussed during pre-submission and interactive review consults.	Improve understanding of the process and expectations.
524	Add wording so It reads: "…should identify at least one Final Reviewer within its organization who is independent from prior review of the project and is responsible for providing a final supervisory assessment…"	The requirement is for an independent final reviewer; but "independent" is not defined.
550	Indicate to whom the 3P organization should provide a copy of all written communications.	The guidance requires that the 3P Organization should provide a copy, but it does not say to whom the copy should be provided. FDA?
674	Reword the sentence to read: "FDA will begin its review of the 3P Review Organization recommendation after it receives all documentation listed above."	Make clear that the FDA "review" is not of the 510(k).

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510(k) Third Party Review Program

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Line(s) No.	Change	Reason
680	Provide examples of when FDA review of a 510(k) submission would be necessary.	To avoid the need for FDA re-review of a 510(k), it is helpful for 3P organizations and 510(k) submitters to understand the circumstances that would necessitate the re-review.
680-721	Make clear that the information beginning with the sentence that starts on line 680 applies only when FDA is required to re-review the 510(k).	
815-817	Delete these sentences.	It is unclear why hiring a person who has worked for a firm that filed a 510(k) (to FDA or a third party) presents the potential for a conflict of interest. This requirement prevents a third party from hiring the most knowledgeable and experienced people.
1185	Add: "…Organization except if required by court of law to testify"	3P could not keep confidential if required to testify.
1192	Add: "…periodic (but at least once every 3 years)…"	Specify a periodic audit of each recognized 3P organization. This assures reasonable monitoring of organization compliance with the guidance requirements.