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September 11, 2020

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

Re: Docket No. FDA-2018-D-2494

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to a request regarding the Food and Drug Administration (FDA or "Agency") Center for Devices and Radiological Health draft guidance *Select Updates for Peripheral Vascular Atherectomy Devices-Pre-market Notification [510(k]Submissions (510(k)]Submissions.* Notice of this draft guidance and request for comments were published in Federal Register Vol. 85, July 13, 2020.

The Advanced Medical Technology Association (AdvaMed) is the world's largest trade association representing medical device and diagnostics manufacturers. AdvaMed's member companies produce the innovations that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed has more than 400 member companies, ranging from the largest to the smallest medical technology innovators and manufacturers. AdvaMed advocates for a legal, regulatory and economic environment that advances global health care by assuring worldwide patient access to the benefits of medical technology. The Association promotes policies that foster the highest ethical standards, rapid product approvals, appropriate reimbursement, and access to international markets.

AdvaMed appreciates the opportunity to comment on the *Select Updates to the Peripheral Vascular Atherectomy Devices* draft guidance and FDA's efforts in preparing the draft guidance. Attachment A lists comments on the draft guidance.

Sincerely,

/s/

Ruey C. Dempsey
Vice President
Technology & Regulatory Affairs

AdvaMed Comments on
"Select Updates for Peripheral Vascular Atherectomy Devices - Premarket Notification [510(k)] Submissions"

Line(s) No.	Change	Reason
116, 117	Replace: "…interventional devices…" Replace with: "…ancillary devices…"	Suggest using consistent terminology between interventional devices and ancillary devices (used in line 125) if they mean the same thing.
162	Clarify or provide examples of what is meant by "qualitative" methodology.	It is unclear what a qualitative methodology for debris removal and collection would be.
179-86	Clarify whether particulate evaluation testing is required for all atherectomy devices, or only those with a coating.	The requirements are unclear as currently described. The focus of the Significance and Recommendation sections is on device coatings, which seems to indicate this testing is only applicable for devices with a coating, but line 196 states that particulate generated by the entire atherectomy system be evaluated.
193	Delete: "…the extremes and an appropriate intermediate size…" Replace with: "…the worst-case size for particulate generation…"	Larger device sizes would generate greater amounts of particulate than smaller sizes, therefore it is unnecessary to test the smallest size and an intermediate size in addition to the largest size. Simply testing the worst-case size would be sufficient.
196	We recommend that you evaluate particulate generated by the ~~entire~~ atherectomy system…	Delete the word or clarify or define what is included in an "entire" system (e.g., components including catheter, etc.)