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

Re: Docket No. FDA-2018-N-0628: Medical Device Submissions: Amending Premarket Regulations That Require Multiple Copies and Specify Paper Copies To Be Allowed in Electronic Format

Dear Sir or Madame:

The Advanced Medical Technology Association (“AdvaMed”) appreciates the opportunity to provide comments on the Food and Drug Administration (“FDA”) proposed rule, “Medical Device Submissions: Amending Premarket Regulations That Require Multiple Copies and Specify Paper Copies To Be Allowed in Electronic Format” (“Proposed Electronic Submission Rule”). As detailed below, we believe that the Proposed Electronic Submission Rule serves goals shared by FDA and its stakeholders and provides benefits that go beyond individual submissions.

AdvaMed is the world’s largest association representing manufacturers of medical devices, diagnostic products, and medical technology. AdvaMed’s member companies range from the largest to the smallest medical product innovators and manufacturers, with nearly 70 percent of our members generating less than $100 million in annual sales. AdvaMed’s member companies produce innovations that transform health care through earlier disease detection, less invasive procedures, and more effective treatments.

AdvaMed commends FDA for its publication of the Proposed Electronic Submission Rule, which serves goals that FDA and its stakeholders share. First, by eliminating multiple paper copies, the Proposed Electronic Submission Rule streamlines the submission process: submitters will file more quickly by avoiding onerous document production while assuring that FDA receives all necessary information in electronic format. This approach is also cost-effective because submitters will avoid the significant expense of paper document production while FDA avoids the significant expense of document storage. More broadly, the Proposed Electronic Submission Rule is good for the environment. Paper submissions often are voluminous, so the proposed rule will save paper and the natural resources used to make it.

With these benefits in mind, AdvaMed suggests a comprehensive listing of submission elements for premarket notifications, as well as submission types for investigational device exemptions and premarket approval applications for which electronic submissions are required. Thus, we recommend revising the first paragraph of Section IV, Description of the Proposed Rule, as follows (revisions in red):

We are proposing to revise FDA’s regulations for devices to remove the requirements for multiple copies of submissions and to instead require one
electronic version. The affected submissions include premarket notification submissions (510(k) submissions) (21 CFR 807.90), including content and format of a 510(k) summary (21 CFR 807.92), content and format of a 510(k) statement (21 CFR 807.93), format of a class III certification (21 CFR 807.94), and confidentiality of information certification (21 CFR 807.95); as well as investigational device exemption applications (21 CFR 812.20); supplemental applications (812.35); reports (21 CFR 812.150); premarket approval applications (PMA) (21 CFR 814.20), including PMA supplements (21 CFR 814.39); reports (21 CFR 814.84); PMA amendments and resubmitted PMAs (21 CFR 814.37); PMA supplements (21 CFR 814.39); humanitarian device exemption applications (21 CFR 814.104); and postapproval requirements and reports (21 CFR 814.126).

We recommend any corresponding changes to the proposed revised regulations that are required to incorporate the additionally-listed regulatory provisions.

As FDA adopts medical device electronic submissions, transparent communications and predictable processes related to establishing stakeholder IT systems, specification change management, and routine maintenance will help assure operational efficiency. Early and continued stakeholder engagement is critical for successful implementation.

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AdvaMed supports the Proposed Electronic Submission Rule and we stand ready to partner with FDA in similar efforts to promote efficiency and preserve resources. Please do not hesitate to contact me at 202-434-7243 or ssilverman@advamed.org if you have any questions.

Respectfully Submitted,

/s/

Steve Silverman
Vice President
Technology & Regulatory Affairs
AdvaMed