

AMERICAN ASSOCIATION OF
NEUROLOGICAL SURGEONS

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American
Association of
Neurological
Surgeons



Congress of
Neurological
Surgeons

CONGRESS OF
NEUROLOGICAL SURGEONS

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March 7, 2019

Scott Gottlieb, MD, Commissioner
Food and Drug Administration (FDA)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

ATTN: Dockets Management Staff (HFA-305)

Subject: Docket FDA-2018-N-0236 Proposed Rule: Medical Device De Novo Classification Process.

Dear Dr. Gottlieb,

The American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) appreciate the opportunity to provide our comments on the Food and Drug Administration's (FDA's) recently released proposed regulation entitled *Medical Device De Novo Classification Process*. Neurosurgery has a long history of collaboration with the agency, as our specialty, highly dependent on medical technology, is one of rapid innovation. We share the common goal of improving patient safety while enhancing efficiency in bringing lifesaving improvements to our patients.

Improvements in the De Novo Process

We commend the agency for publishing the proposed regulation to undertake a comprehensive approach to strengthen and clarify the De Novo pathway through formal rulemaking. We appreciate the fact that the FDA no longer requires a manufacturer to first submit and receive a denial for a 510(k) application in order to access the De Novo process, if they can show that there is no legally marketed device to use as a predicate. This makes sense and is much more efficient than the former prerequisite to submit a 510(k) application and wait for a denial because of the lack of a substantially equivalent device before being permitted to apply as a De Novo device. We support the agency's work to develop multiple pathways for products to come to market to address patient needs. A more effective De Novo path will help create modern and useful predicate devices to give patients timely access to safe and effective medical devices to improve their health.

Requirements for Data

We note that the De Novo proposed rule includes provisions that would require the following elements be submitted:

- a bibliography of all published and unpublished reports on the device and any other information relevant to a device's safety or effectiveness;
- samples of the device and its components, if requested by FDA; and
- advertisements for the device.

The AANS and the CNS are supportive of requirements for a thorough review of existing data but the requirement that “all” available data be submitted should be clarified to indicate that which is reasonably attainable by the applicant. Requirements to submit advertising and models may be appropriate for a high-risk device that would more likely undergo pre-market application (PMA) approval but it is not clear that they are necessary for the De Novo pathway.

Conclusion

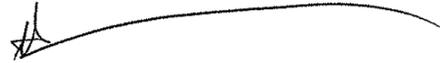
The AANS and the CNS have a deep respect for the professionalism, knowledge, dedication and hard work of the men and women at the FDA. We continue to stand ready to assist the FDA with neurosurgical expertise and appreciate our collaborative and collegial partnership with the agency. We commend the agency for bringing greater certainty to the De Novo process. However, as you move forward with finalizing the proposed rule, we urge you to take the least burdensome approach for devices which are eligible for the De Novo clearance process.

Thank you for considering our comments.

Sincerely,



Shelly D. Timmons, MD, PhD, President
American Association of Neurological Surgeons



Ganesh Rao, MD, President
Congress of Neurological Surgeons

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