KING & SPALDING LLP

King & Spalding LLP
101 Second Street
Suite 2300
San Francisco, CA 94105
Main: 415/318-1200
Fax: 415/318-1300

Elaine H. Tseng, Esq.
Partner
Direct Dial: 415/318-1240
etseng@kslaw.com

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Food and Drug Administration
Dockets Management Staff (HFA-305)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2011-N-0776 (request for comments by May 7, 2018)

To Whom It May Concern:

King & Spalding appreciates the opportunity to submit this comment on FDA's notice regarding the above-referenced docket, titled "Agency Information Collection Activities; Proposed Collection; Comment Request; Reclassification Petitions for Medical Devices" (83 Fed. Reg. 9743, March 7, 2018). This notice invites public comment on the necessity and utility of information collected by FDA in connection with the reclassification process.[1]

FDA's notice references the Forms FDA-3427 (Supplemental Data Sheet) and FDA-3429 (Device Classification Questionnaire), on which submitters have long provided, and currently still provide, information to help inform FDA's review of petitions for device reclassification. As mentioned in the notice, in 2014, FDA proposed to eliminate the use of these Forms; however, the Agency has not, to date, finalized this proposal.[2] We respectfully submit that these Forms should continue to be required, as they seek information from petitioners that is essential to enable a robust assessment of whether reclassification would provide reasonable assurance of device safety and effectiveness. In particular:

[1] See 83 Fed. Reg. 9744.
[2] See Id. at 9744-45.

- These Forms call for petitioners to provide critical information about whether a device would be reasonably safe and effective under a changed classification and, thus, whether reclassification would be appropriate and satisfy applicable legal and regulatory standards.
- Examples of critical information required by the Forms include identification of the risks to health presented by the device[3]; whether and what special controls are needed and can be established to permit any reclassification to Class II[4]; what restrictions on use of the device would be needed in the event of reclassification (e.g., special labeling, use by persons with specific training or experience)[5]; and clinical experience and judgment relevant to the reclassification request.[6]
- At present, the Forms must, by regulation, be completed by any petitioner seeking reclassification of a medical device. See 21 CFR 860.123(a)(3) and (4). There is no clear requirement elsewhere in FDA's reclassification petition regulation (21 CFR 860.123) for petitions to supply specific information sought in the Forms.
- Manufacturers seeking reclassification may have information about pertinent matters (e.g., risks to health) beyond that otherwise known to FDA. Thus, the current Agency practice of soliciting this information from petitioners via the Forms is also important for this reason.

In sum, several reasons support the continued use of Forms FDA-3427 and FDA-3429. FDA's 2014 proposal to eliminate use of these forms acknowledged that the need for the forms could be eliminated, but only if certain other changes were made to FDA's regulations.[7] FDA's regulations have not been amended in relevant ways and, as noted above, absent continued use of the Forms, there is no clear requirement for petitioners to provide specific information requested therein and necessary to inform potential device reclassification.

We appreciate the Agency's thoughtful consideration of this comment.

Sincerely,

Elaine H. Tseng
Partner

[3] See Form FDA-3427, item 5, and Form FDA-3429, question 3.
[4] See Form FDA-3429, items 5 and 6.
[5] See FDA Form-3427, item 9, and FDA Form-3429, item 10.
[6] See FDA Form-3427, item 8.
[7] 79 Fed. Reg. 16252, 16256 (March 25, 2014). We note that certain comments submitted on this proposal also objected to discontinuation of use of the Forms. *See, e.g.*, comment of AdvaMed in Docket No. FDA–2013–N–1529.