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

Re: Docket No. FDA–2016–N–0400: General and Plastic Surgery Devices; Reclassification of Blood Lancets

To Whom It May Concern:

The Advanced Medical Technology Association ("AdvaMed") appreciates the opportunity to provide comment on the Food and Drug Administration's ("FDA" or "Agency") Proposed Order: General and Plastic Surgery Devices; Reclassification of Blood Lancets ("Proposed Order").[1] AdvaMed represents 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 treatment. Our members range from the smallest to the largest medical technology innovators and companies.

These comments are limited solely to the procedural aspects associated with the Proposed Order should the Agency proceed with this rulemaking. These comments should not be construed as approval or disagreement with other aspects of the Proposed Order, such as the justification for reclassification or the proposed special controls.

I. IMPLEMENTATION TIMELINE

The Proposed Order states that it will become effective on its publication date, and that the Agency "does not intend to enforce compliance with the 510(k) requirement or special controls until 180 days after the effective date of the final order." 81 Fed. Reg. at 11148. We do not believe 180 days provides sufficient time for a manufacturer to determine requirements, assemble the required documentation, meet the labeling requirements, submit a 510(k), and obtain a determination of substantial equivalence.

It is also likely that manufacturers will need to meet with FDA for a pre-submission meeting to ensure alignment on the submission's content. Such a meeting cannot occur before the Proposed Order is made final, as all relevant information will not be available until that time. In addition to drafting and submitting the meeting request based on the final Order, FDA will

[1] General and Plastic Surgery Devices; Reclassification of Blood Lancets, Proposed Order, 81 Fed. Reg. 11140 (March 3, 2016) *available at* https://www.gpo.gov/fdsys/pkg/FR-2016-03-03/pdf/2016-04578.pdf.

also need to schedule the meeting, and the manufacturer is likely to require time to address feedback provided by the Agency during the meeting prior to submitting the 510(k) for review.

In light of the above, we recommend FDA provide an 18-month transition period for manufacturers to obtain 510(k) clearance for affected devices. Extending the time period is in the best interest of the public, as it will promote the uninterrupted supply of these devices to consumers during a reclassification transition.

II. UDI CONSIDERATIONS

Reclassifying lancets as class II devices raises a number of questions related to unique device identification ("UDI") implementation. The Proposed Order does not address these UDI issues, and we believe it is imperative that FDA ensure UDI implementation for these products is fair, predictable, and consistent with the intent of the Agency's UDI rules. In this regard, should FDA proceed with this rulemaking, the final Order should state that lancets can utilize their Universal Product Code ("UPC") as the UDI, and these requirements will not begin until September 24, 2018.

21 C.F.R. § 801.40(d) permits class I devices to utilize a UPC for purposes of UDI compliance. However, without an FDA-granted exception, class II devices cannot take advantage of this provision of the rules and therefore must comply with more intensive UDI labeling requirements, which include: Obtaining a UDI from an accredited issuing agency; adding the UDI to the product's labeling; updating production equipment to account for the UDI; potentially removing reimbursement codes (*e.g.*, national drug code numbers); and managing inventory of old and new product.

During the public comment process of the final UDI rule, FDA and industry anticipated that lancets would use the product's UPC for purposes of UDI implementation. Without any further discussion in the Proposed Order, FDA has not provided a reasonable basis to remove these products from the benefits provided in 21 C.F.R. § 801.40(d). As a result, we believe the Agency should provide an exception to its UDI rules, pursuant to 21 C.F.R. § 801.55, to allow lancets, regardless of their classification, to utilize a UPC as its UDI.

Moreover, as class I devices, lancets are not currently subject to the UDI rules until September 24, 2018, including data submission requirements to the Global Unique Device Identification Database ("GUDID"). In order to minimize supply chain interruptions and reduce onerous burdens on device manufacturers, FDA should not require these products, regardless of their classification, to comply with the class I UDI rules until September 24, 2018, the date that lancet manufacturers have been planning for since 2011.

While we strongly support permitting lancets to utilize their UPC as the product's UDI beginning September 24, 2018, should FDA disagree and require lancets to comply with the UDI rules as they apply to class II devices, FDA must provide manufacturers with a three-year transition period beginning on the date the final Order is issued, similar to the implementation period FDA provided class II device manufacturers when issuing its final

UDI rules. *See* 78 Fed. Reg. 58786, 58816 (Sep. 24, 2013). The Agency recognized during the UDI Final Rule implementation that three years is an appropriate amount of time for a manufacturer to ensure its processes are in place to comply with the UDI rules for class II devices. As such, the same transition period should be provided to lancet manufacturers should they become subject to the class II requirements of the UDI rules. Without this transition period, lancets could become immediately subject to the UDI rules because the class II UDI requirements begin on September 24, 2016. Immediately subjecting lancets to UDI labeling requirements upon issuance of a final Order would be significantly disruptive to the supply chain and pose an unreasonable burden on manufacturers.

Based on the above discussion, it is imperative that, should FDA reclassify lancets as class II devices, adequate timelines must be provided for submission of a 510(k) and compliance with relevant UDI rules. Failure to account for these issues could disrupt access to these important devices during the reclassification period.

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AdvaMed would like to thank the FDA for its consideration of these comments. Please do not hesitate to contact me at 202-434-7224 or zrothstein@advamed.org if you have any questions.

Respectfully submitted,

/s/

Zachary A. Rothstein, J.D.
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Attachment