



5 November 2018

(18-6926)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. Notifying Member: UNITED STATES OF AMERICA If applicable, name of local government involved (Article 3.2 and 7.2):
2. Agency responsible: Food and Drug Administration (FDA), Health and Human Services (HHS) [1436] Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above: Please submit comments to: USA WTO TBT Enquiry Point, Email: usatbtep@nist.gov
3. Notified under Article 2.9.2 [], 2.10.1 [], 5.6.2 [X], 5.7.1 [], other:
4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Ultrasound cyclodestructive device; Quality (ICS 03.120), Medical equipment (ICS 11.040).
5. Title, number of pages and language(s) of the notified document: Ophthalmic Devices; Reclassification of Ultrasound Cyclodestructive Device (6 page(s), in English)
6. Description of content: The Food and Drug Administration (FDA) is issuing this proposed order to reclassify the ultrasound cyclodestructive device, a postamendments class III device (regulated under product code LZR), into class II (special controls), subject to premarket notification. FDA is also identifying the proposed special controls that the Agency believes are necessary to provide a reasonable assurance of safety and effectiveness of the device. FDA is proposing this reclassification on its own initiative based on new information. If finalized, this order will reclassify these devices from class III to class II (special controls) and reduce regulatory burdens as these types of devices will no longer be required to submit a premarket approval application (PMA) but can instead submit a less burdensome premarket notification (510(k)) before marketing their device.
7. Objective and rationale, including the nature of urgent problems where applicable: Consumer information, labelling; Protection of human health or safety
8. Relevant documents: 83 Federal Register (FR) 48403, 25 September 2018; Title 21 Code of Federal Regulations (CFR) Part 886.
9. Proposed date of adoption: To be determined Proposed date of entry into force: To be determined
10. Final date for comments: 26 November 2018
11. Texts available from: National enquiry point [] or address, telephone and fax numbers and email and website addresses, if available, of other body: https://members.wto.org/crnattachments/2018/TBT/USA/18_5716_00_e.pdf