WORLD TRADE ORGANIZATION

G/TBT/N/USA/1424

15 November 2018

(18-7192)

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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) [1448] **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 [ ], 5.7.1 [ ], other: [X]**
4.	**Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Intranasal electrostimulation device for dry eye symptoms; Medical equipment (ICS 11.040).
5.	**Title, number of pages and language(s) of the notified document:** Medical Devices; Ophthalmic Devices; Classification of the Intranasal Electrostimulation Device for Dry Eye Symptoms (3 page(s), in English)
6.	**Description of content:** The Food and Drug Administration (FDA or we) is classifying the intranasal electrostimulation device for dry eye symptoms into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the intranasal electrostimulation device for dry eye symptoms' classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety
8.	**Relevant documents:** • 83 Federal Register (FR) 52973, 19 October 2018; Title 21 Code of Federal Regulations (CFR) Part 886.
9.	**Proposed date of adoption:** 17 May 2018 **Proposed date of entry into force:** 19 October 2018
10.	**Final date for comments:** None
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_5918_00_e.pdf