July 24, 2018

Connie Hoy
Official Correspondent
Cynosure, Inc.
5 Carlisle Road
Westford, MA 01886

Document Number: CPT1800139

Dear Ms. Hoy:

It has come to our attention that you may be marketing the DEKA SmartXide^2 Laser System (MonaLisa Touch), which meet the definition of a device as that term is defined in section 201(h) of the Federal Food Drug and Cosmetic Act (FD&C Act), in a manner that potentially violates the FD&C Act.

Specifically, the DEKA SmartXide^2 Laser System (MonaLisa Touch) was cleared (K133895) for incision, excision, ablation, vaporization and coagulation of body soft tissues in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynaecology, neurosurgery, orthopaedics, general and thorasic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery. However, we have conducted a review of our files and are unable to identify an additional Food and Drug Administration (FDA) clearance or approval supporting the use of the claims located http://www.smilemonalisa.com/ such as the following:

- "MonaLisa Touch is the only technology for vaginal and vulvar health with over 18+ published clinical studies."
- "MonaLisa Touch is a simple, safe, and clinically proven laser treatment for the painful symptoms of menopause, including intimacy."
- 'During a treatment, a vaginal probe is inserted into the patient's vagina, and delivers gentle, virtually painless laser energy to the vaginal wall, stimulating a healing response."
- "It penetrates the wall of the vagina, and stimulates cells that are important in creating fluid, improving collagen synthesis."
- "Fibroblasts activate biosynthesis of new collagen and produce main components of ground substance."

Also, the tip of the sterilized applicator that is inserted through the vulva and moved along the vaginal canal in an outward motion, applying the laser in a 360-degree pattern to the vaginal wall, appears to have been modified from the previous cleared device.

We request that you provide us with the following information:

- FDA clearance or approval number for the DEKA SmartXide^2 Laser System (MonaLisa Touch) for the additional claims referenced above.

- The basis for your determination of whether or not you are required to obtain FDA clearance or approval for the DEKA SmartXide^2 Laser System (MonaLisa Touch) for the additional claims referenced above.

In addition, we request that a written response be submitted within 30 days of receipt of this letter. The response and any further correspondence regarding this matter should reference the Document Number, listed above, and should be submitted to:

Complaints Program Manager, WO66-3684
Division of Analysis and Program Operations
Office of Compliance
Center for Devices and Radiological Health
10903 New Hampshire Avenue
Silver Spring, MD 20993

If you have questions relating to this matter, you may contact CDR Cesar Perez at 301-796-5770, or log onto our web site at www.fda.gov for general information relating to FDA device requirements.

Sincerely,

Cesar A. Perez -S

Digitally signed by Cesar A. Perez -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Cesar A. Perez -S, 0.9.2342.19200300.100.1.1=2000613874
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CDR Cesar A. Perez, PhD
Chief
Surveillance and Enforcement Branch I
Division of Premarket and Labeling Compliance
Office of Compliance
Center for Devices and Radiological Health