July 24, 2018

For updated information refer to: https://www.fda.gov/medical-devices/safety-communications/fda-warns-against-use-energy-based-devices-perform-vaginal-rejuvenation-or-vaginal-cosmetic

Lior Dayan
CEO
Alma Lasers
485 Half Day Road, Suite 100
Buffalo Grove, IL 60089

Document Number: CPT1800705

Dear Mr. Dayan:

It has come to our attention that you may be marketing the Alma Lasers Pixel CO_2 Laser System (FemiLift), 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 Alma Lasers Pixel CO_2 Laser System (FemiLift) was cleared (K103501) for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic surgery (dermatology and plastic surgery), podiat1y, gynecology, neurosurgery, orthopedics (soft tissue), arthroscopy (knee). 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 on http://www.almalasers.com/us/feminine-health/ such as the following:

- "FEMILIFT is a laser assisted procedure designed to improve vaginal irregularities through vaporization and thermal effect using a CO_2 laser."

- "The Alma FemiLift is a breakthrough technology using an Alma CO_2 laser to deliver fractionated light and thermal energy to assist in vaginal mucosa revitalization."

We request that you provide us with the following information:

- FDA clearance or approval number for the Alma Lasers Pixel CO_2 Laser System (FemiLift) 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 Alma Lasers Pixel CO_2 Laser System (FemiLift) 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

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

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
Date: 2018.07.24 12:37:31 -04'00'

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