



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>

Ahava Stein
A. Stein – Regulatory Affairs Consulting
Inmode MD Ltd.
20 Hataas Str. (Suite 102)
Kfar Saba, Israel 44425

Document Number: CPT1800704

Dear Mr. Stein:

It has come to our attention that you may be marketing the FormaV and FractoraV lasers, 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, we have conducted a review of our files, and have been unable to identify any Food and Drug Administration (FDA) clearance or approval for the FormaV and FractoraV lasers as currently marketed on the website, <https://inmodemd.com/treatment/feminine-wellness/>, for therapeutic use in the treatment of sexual dysfunction, vaginal rejuvenation and urinary stress inconstance.

We request that you provide us with the following information:

- FDA clearance or approval number for the FormaV and FractoraV lasers.
- The basis for your determination of whether or not you are required to obtain FDA clearance or approval for the FormaV and FractoraV lasers.

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

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 12:53:14 -04'00'

-S

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

Cc:

Harel Gadot

U.S. Agent

A. Stein – Regulatory Affairs Consulting

C/O Medx Ventures

175 Derby St. Unit 27 Suite 1

Hingham, MA 02043