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

Paul Herchman
Chief Executive Officer
Thermigen, Inc.
3131 West Royal Lane, Suite 100
Irving, TX 75063

Document Number: CPT1800703

Dear Mr. Herchman:

It has come to our attention that you may be marketing the THERMIva, 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 THERMIva was cleared (K130689-Symphoni RF Generator) for use in dermatological and general surgical procedures for electrocoagulation and hemostasis and to create lesions in nervous tissue when used in combination with Neuro Therm (previously Smith&Nephew) thermal/coagulation probes. 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 "vaginal rejuvenation" claims located on the website, https://www.thermiva.com/.

We request that you provide us with the following information:

- FDA clearance or approval number for the THERMIva 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 THERMIva 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
Date: 2018.07.24 12:45:47 -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