July 26, 2018

David Chmel
Official Correspondent
BTL Industries, Inc.
362 Elm Street
Marlborough, MA 01752

Document Number: CPT1800792

Dear Mr. Chmel:

It has come to our attention that you may be marketing the Exilis (Exilis Ultra 360), 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 Exilis (Exilis Ultra 360 System) device was cleared (K092191) for the primary treatment of dermatologic and general surgical procedures for non-invasive treatment of wrinkles and rhytids. 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 the website, https://pelvicsuite.com/products/pelvic-suite/ultra-femme-360/ such as the following:

- "What is Ultra Femme 360? A whole new approach to women's intimate health. The procedure provides the shortest non-invasive radio frequency treatment available for female intimate parts."

- "The Exilis Ultra 360 system is proven to increase elastin and collagen in the treatment area."

We request that you provide us with the following information:

- FDA clearance or approval number for the Exilis (Exilis Ultra 360 System) device 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 Exilis (Exilis Ultra 360 System) 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: 2018.07.26 08:19:37 -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