July 24, 2018

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

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

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

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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

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

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
Date: 2018.07.24 12:42:34 -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

U.S. FOOD & DRUG ADMINISTRATION

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

July 24, 2018

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 inconsistence.

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 -S

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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'

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

U.S. FOOD & DRUG ADMINISTRATION

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

July 24, 2018

James Hobart, PhD
Co-Founder and Chief Executive Officer
Sciton, Inc.
925 Commercial Street
Palo Alto, CA 94303

Document Number: CPT1800706

Dear Dr. Hobart:

It has come to our attention that you may be marketing the JOULE Multi-Platform System, which meets 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 JOULE Multi-Platform System was cleared (K101916) as a laser/light powered device for multiple general uses. However, we have conducted a review of our files and are unable to identify an additional Food and Drug Administration (FDA) clearance or approval number supporting the use of the JOULE Multi-Platform System for DiVa Laser Vaginal Therapy as specified on the website, https://sciton.com/diva/.

We request that you provide us with the following information:

- FDA clearance or approval number for the JOULE Multi-Platform System 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 JOULE Multi-Platform System 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 12:29:25 -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

July 24, 2018

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

August 01, 2018

Yoni Iger
Venus Concept, Ltd.
Hayetsira Street, Bld. 2
Yokneam Illit, Israel 2066728

Document Number: CPT1800784

Dear Mr. Iger:

It has come to our attention that you may be marketing the Venus Fiore System, which meets 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 Food and Drug Administration (FDA) clearance or approval for the Venus Fiore System as marketed on the website (as of 7/24/18), https://www.venusconcept.com/en-gl/venus-fiore.htm, for internal vaginal health restoration, labia skin tightening, and mons pubis reduction.

We request that you provide us with the following information:

- FDA clearance or approval number for the Venus Fiore System.
- The basis for your determination of whether or not you are required to obtain FDA clearance or approval for the Venus Fiore System.

We appreciate that you have already contacted us to begin modifications to your website.

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

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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: 2018.08.01 17:39:41 -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

Cc.

Horacio Gaspar
U.S. Agent
Venus Concept USA Inc.
1880 N. Commerce Parkway, Suite 2
Weston, FL 33326