Dominion Aesthetic Technologies, Inc.
Ahmed Mohammed
VP, Product Development
2431 Aloma Avenue Suite 225
Winter Park, Florida 32792

August 11, 2022

Re: K211681
Trade/Device Name: EON
Regulation Number: 21 CFR 878.5400
Regulation Name: Low level laser system for aesthetic use
Regulatory Class: Class II
Product Code: PKT

Dear Ahmed Mohammed:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated March 30, 2022. Specifically, FDA is updating this SE Letter to remove OOK and GEX as an administrative correction, because OOK (Dermal Cooling Pack/Vacuum/Massager) and GEX (Powered Laser Surgical Instrument) do not apply to your device.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Long Chen, Ph.D., OHT4: Office of Surgical and Infection Control Devices, 301-796-6389, Long.Chen@fda.hhs.gov.

Sincerely,

Long H. Chen -S
Digitally signed by Long H. Chen -S
Date: 2022.08.11 13:57:54 -04'00'

Long Chen, Ph.D.
Director (Acting)
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

March 30, 2022

Dominion Aesthetic Technologies, Inc.
Ahmed Mohammed
VP, Product Development
2431 Aloma Avenue Suite 225
Winter Park, Florida 32792

Re: K211681
Trade/Device Name: EON
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: GEX, OOK, PKT
Dated: February 28, 2022
Received: February 28, 2022

Dear Ahmed Mohammed:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Purva U. Pandya -S

Purva Pandya, D.Eng.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211681

Device Name
EON

Indications for Use *(Describe)*
The EON (1064nm laser) is intended for non-invasive lipolysis of the abdomen and flanks to achieve disruption of adipocyte cells intended for non-invasive aesthetic use to achieve a desired aesthetic effect. It is intended for individuals with a Body Mass Index of 30 or less.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 5: 510(k) Summary

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5-1 Submitter

Dominion Aesthetic Technologies, Inc.

2431 Aloma Avenue Suite # 300

Winter Park, FL 32792

Contact Person: Ahmed Mohammed

Phone: 763-439-4602

Email: amohammed@dominionaethetic.com

Date Prepared: March 15, 2022

5-2 Device Information

Name of Device: EON.

Common or Usual Name: Aesthetic Laser System

Classification Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology (21 CFR 878.4810)

Regulatory Class: II

Product Code: GEX, OOK and PKT

5-3 Predicate Device

Cynosure, Inc., Sculpsure, K160470

5-4 Device Description

EON aesthetic laser system is 1064nm diode laser device that is intended for non-invasive lipolysis of the abdomen and flanks in individuals with a Body Mass Index (BMI) of 30 or less. This wavelength is used to affect the appearance of visible fat bulges in the abdomen and flanks.

Both laser energy and cooling air are delivered concurrently through the same treatment head that is positioned by a robotic arm. The treatment head is never in contact with the skin.

During treatment, the desired area will be defined by the physician and will be treated with the 1064nm laser over a 20-minute timeframe. The mechanism of action is to preferentially heat the adipose tissue to temperatures that will induce apoptosis (42°C to 50°C). The cooling system will maintain the skin at comfortable temperature (<43°C).

5-5 Indications for Use

The EON (1064nm laser) is intended for non-invasive lipolysis of the abdomen and flanks to achieve disruption of adipocyte cells intended for non-invasive aesthetic use to achieve a desired aesthetic effect. It is intended for individuals with a Body Mass Index of 30 or less.

5-6 Comparison of Technological Characteristics with the Predicate Device

Parameter	Dominion EON	Cynosure, Inc. SculpSure	Comparison
Indications for Use (IFU)	The EON (1064nm laser) is intended for non-invasive lipolysis of the abdomen and flanks to achieve disruption of adipocyte cells intended for non-invasive aesthetic use to achieve a desired aesthetic effect. It is intended for individuals with a Body Mass Index of 30 or less.	Cynosure SculpSure is a diode laser system intended for non-invasive lipolysis of the abdomen and flanks in individuals with a Body Mass Index (BMI) of 30 or less. The device is intended to affect the appearance of visible fat bulges in the abdomen and flanks.	Similar
K Number	K211681	K160470	N/A
Lipolysis Method	Heat-assisted	Heat-assisted	Same
Laser Type	Diode	Diode	Same
Wavelength	1064 nm	1064 nm	Same
Power Mode	Continuous Wave (CW)	Continuous Wave (CW)	Same
Pulse Length	1 to 20s	1 to 20s	Same

Parameter	Dominion EON	Cynosure, Inc. SculpSure	Comparison
Applicator Size	75 cm^2, 110 cm^2, 150 cm^2	24 cm^2 (4X)	Similar
Application Method	Articulated Scanning Arm, Non-contacting	Belt	Different: EON uses an articulated scanning arm to continuously move the laser beam over the treatment area and, simultaneously, provide skin cooling. EON is similar to SculpSure in principal of operation where both devices deliver laser energy and cool down the skin in the treated area. To ensure safety, EON monitors skin temperature and turn off the laser if the skin temperature exceeds 43°C. EON uses jet impingement cooling (which is more effective than contact cooling), this ensures that the skin in the treated area is safe and comfortable while the laser energy is heating the subcutaneous adipose tissue. EON is as safe, and as effective as SculpSure.
Treatment Area	Abdomen and Flanks	Abdomen and Flanks	Same
Maximum Power Density	Up to 1.4 W/cm^2	Up to 1.4 W/cm^2	Same

Parameter	Dominion EON	Cynosure, Inc. SculpSure	Comparison
Supply Voltage	110 V; Single Phase	220 V; Single Phase	Different: EON uses 110V supply voltage to improve usability since 110V is the standard supply voltage the United States. Supply voltage doesn't affect efficacy. EON design meets all applicable electrical safety standards.
Supply Current	20A	20A	Same
Laser Cooling	Closed cycle, internal	Closed cycle, internal	Same

5-7 Performance Data

5.7.1 Electrical Safety and Electromagnetic Compatibility (EMC) Testing Conducted

- IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance
- IEC 60601-1 :2005 (Third Edition) + CORR. 1 :2006 + CORR. 2:2007 +A1 :2012 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1: 2012 reprint) including compliance with US National Differences demonstrating conformance to the FDA-recognized standard for electrical safety (AAMI/ANSI ES60601-1:2005(R) 2012).

5.7.2 Software Validation & Verification

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Moderate" level of concern, since a failure or latent design flaw could directly result in minor injury to the patient or operator.

5.7.3 Other Non-Clinical Testing Conducted

- IEC 60601-2-22 Edition 3.1 2012-10 Medical Electrical Equipment - Part 2-22: Particular Requirements for Basic Safety and Essential Performance of Surgical, Cosmetic, Therapeutic and Diagnostic Laser Equipment
- IEC 60825-1 :2014 (Third Edition) Safety of Laser Products - Part 1: Equipment Classification and Requirements

5.7.4 Summary of the Clinical Study Conducted

5.7.4.1 Objectives

The primary objective of this study was to confirm the safety of a1064-nm laser device with a novel robotic arm for noninvasive subcutaneous fat reduction in the flank area. Secondary objectives included assessing the extent of subject discomfort during treatment, overall subject satisfaction with the results of the procedure, and a determination of subcutaneous fat reduction in the treated area.

5.7.4.2 Efficacy Endpoints

Primary efficacy endpoint: blinded evaluation of pre- and post-treatment photos

Secondary efficacy endpoints: mean fat reduction by ultrasound and subject satisfaction.

5.7.4.3 Materials and Methods

A 110-cm^2 area on both flanks of enrolled subjects was treated for 20 minutes with an FDA-cleared robotic non-contact 1064-nm laser system (EON®; Dominion Aesthetic Technologies, Inc.). Patients were followed for 12 weeks, and examined routinely at 2 weeks, 12 weeks and additionally as needed, post-treatment. Pre- and post-treatment photos were taken by a professional photographer using a standardized DSLR and lighting set-up. The ability of three independent readers to correctly identify blinded pre-treatment vs. post-treatment photos was assessed. The study was declared to be a success if at least two of the three independent readers correctly identified at least 9 of the 11 photos as pre-treatment. Ad hoc surveys were administered to assess patient satisfaction. A 2-week post-treatment ultrasound scan was used to check for changes in the treated area. The study was powered to assess patient-level and flank-level subcutaneous adipose tissue thickness using ultrasound measurements taken at a center of each treatment zone prior to treatment and at 12 weeks post-treatment for efficacy determination, with mean thicknesses calculated per subject and per flank.

5.7.4.4 Results

The treatment had a low incidence of adverse effects, with only one subject developing a palpable thickening in the subcutaneous tissue following treatment. This was noted at the two-week time period and had resolved by the 12-week post-treatment exam. No other predefined adverse effects were noted. On a scale of 0 to 10, the mean pain score during the procedure was 1.95, decreasing to 0.9 at 30 minutes post-procedure. Subject satisfaction was “Excellent” for all subjects (100%). For blinded evaluation of pre- and post-treatment photos, 27 (81.8%) of 33 image sets were correctly scored overall, with two of the three readers correctly identifying pre- and post-treatment photos in at least 9 of the 11 subjects, thus achieving study success. At Week 12 after one treatment, the mean reduction in

subcutaneous adipose thickness on the treated flanks was 6.1 mm per flank and 12.1 mm per patient (-15%; $p<0.01$, both measures).

Similar to the prior abdominal study with the same robotic laser device, this study confirms the safety of this 1064-nm non-contact laser device for treating subcutaneous fat on the flanks. The study provided objective evidence of EON safety and efficacy in treating the flank area.

5-8 Conclusions

The clinical and non-clinical testing conducted on EON support the safety of the device and the hardware and software verification and validation demonstrate that EON should perform as intended in the specified use conditions. Dominion believes that EON is as safe, as effective, and performs as well as the predicate device. The clinical performance of EON demonstrates that EON has a safety and effectiveness profile that is similar to its predicate device. It has been concluded that the EON device is safe and effective for its intended use.