February 17, 2023

Dominion Aesthetic Technologies, Inc.
Ahmed Mohammed
VP, Product Development
2431 Aloma Avenue Suite 300
Winter Park, Florida 32792

Re: K222226
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
Dated: January 19, 2023
Received: January 19, 2023

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); 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,

Jianting Wang -S

Jianting Wang
Acting 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)*

K222226

Device Name
EON

Indications for Use *(Describe)*

The EON (1064nm laser) is intended for non-invasive lipolysis of the abdomen, flanks, back, and thighs 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.

510(k) Summary: K222226

Submitter

Dominion Aesthetic Technologies, Inc.

2431 Aloma Avenue Suite # 300

Winter Park, FL 32792

Establishment registration number (3016249961)

Contact Person: Ahmed Mohammed

Phone: 763-439-4602

Email: amohammed@dominionaethetic.com

Date Prepared: February 10, 2023

Device Information

Name of Device: EON.

Common or Usual Name: Aesthetic Laser System

Classification Name: Low level laser system for aesthetic use (21 CFR 878.5400)

Regulatory Class: II

Product Code: PKT

Predicate Device

Dominion Aesthetic Technologies, Inc., K211681

Device Description

EON aesthetic laser system is 1064nm diode laser device that is intended for non-invasive lipolysis of the abdomen, flanks, back, and thighs 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 and moved over the skin at a fixed height 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). The cooling system will maintain the skin at comfortable temperature (<43°C).

Indications for Use

The EON (1064nm laser) is intended for non-invasive lipolysis of the abdomen, flanks, back, and thighs 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.

Comparison of Technological Characteristics with the Predicate Device

Parameter	Dominion EON (K222226)	Dominion EON (K211681)
Indications for Use	The EON (1064nm laser) is intended for non-invasive lipolysis of the abdomen, flanks, back, and thighs 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.	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.
K Number	K222226	K211681
Lipolysis Method	Heat-assisted	Heat-assisted
Laser Type	Diode	Diode
Wavelength	1064 nm	1064 nm
Power Mode	Continuous Wave (CW)	Continuous Wave (CW)
Pulse Length	1 to 20s	1 to 20s
Applicator Size	75 cm^2, 110 cm^2, 150 cm^2	75 cm^2, 110 cm^2, 150 cm^2
Application Method	Articulated Scanning Arm, Non-contacting	Articulated Scanning Arm, Non-contacting
Treatment Area	Abdomen, flanks, back, thighs, and arms	Abdomen, flanks
Maximum Power Density	Up to 1.4 W/cm^2	Up to 1.4 W/cm^2
Supply Voltage	110 V; Single Phase	110 V; Single Phase
Supply Current	20A	20A
Laser Cooling	Closed cycle, internal	Closed cycle, internal

Non-Clinical Performance Data

EON was previously cleared by FDA for use in Abdomen [K180511] and for use in Abdomen and Flanks [K211681]. There has been no change to the EON design since the most recent FDA Clearance [K211681].

Clinical Performance Data

Literature was used to support the addition of the two proposed areas (thighs and back).

Conclusions

Dominion believes that EON is as safe, as effective, and performs exactly the same as the predicate device. The clinical justification concluded that the performance of EON in the proposed areas (back and thighs) has a safety and effectiveness profile that is similar to its performance in the previously cleared areas. It has been concluded that the EON device is safe and effective for its (proposed) intended use.