



August 12, 2022

Dominion Aesthetic Technologies, Inc.
Ahmed Mohammed
Vice President of Quality and Regulatory
2431 Aloma Avenue Suite 225
Winter Park, Florida 32792

Re: K180511

Trade/Device Name: Eon™ FR
Regulation Number: 21 CFR 21 CFR 878.5400
Regulation Name: Low level laser system for aesthetic use
Regulatory Class: Class II
Product Code: PXT

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 June 12, 2019. 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 and correcting the Trade Name.

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: 2022.08.12 16:53:28 -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



Dominion Aesthetic Technologies, Inc.
Ahmed Mohammed
Vice President of Quality and Regulatory
2431 Aloma Avenue Suite # 225
Winter Park, Florida 32792

June 12, 2019

Re: K180511

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: June 3, 2019
Received: June 3, 2019

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,

Neil R

Ogden -S

Neil R. P. Ogden

Acting Assistant Director

Light Based Energy Devices Team

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

Digitally signed by

Neil R Ogden -S

Date: 2019.06.12

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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number (if known)

K180511

Device Name

eon™ FR

Indications for Use (Describe)

The eon™ FR (1064nm laser) is intended for non-invasive lipolysis of the abdomen 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 (BMI) 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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