February 27, 2025

XOD Inc.
% Angela Blackwell
Senior Consultant
Blackwell Device Consulting
P.O. Box 718
Gresham, Oregon 97030-0172

Re: K242175
Trade/Device Name: XOD Diathermia Radiofrequency Device
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: PBX
Dated: January 21, 2025
Received: January 21, 2025

Dear Angela Blackwell:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

James H. Jang -S
Digitally signed by James H. Jang -S
Date: 2025.02.27 13:38:15 -05'00'

For
Long Chen, Ph.D.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242175

Device Name

XOD Diathermia Radiofrequency Device

Indications for Use *(Describe)*

The XOD diathermia radiofrequency device is intended to provide topical heating for the purpose of elevating tissue temperature for the treatment of selected medical conditions such as relief of pain, muscle spasms, and increase in local circulation. The XOD device also is intended to provide a temporary reduction in the appearance of cellulite.

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.

XOD Diathermia Radiofrequency Device
510K Summary
February 25, 2025

Name and Address: XOD Inc.
3245 Amber St.
Philadelphia, PA 19134
Contact Person: Ron Gardi
Email: info@xod.life
Telephone: 888-460-9042

Name of device: XOD Diathermia Radiofrequency Device
Classification Name: massager, vacuum, radio induced heat
CFR: 21 CFR 878.4400
Primary Product Code: PBX

Submission Contact:
Angela Blackwell
Blackwell Device Consulting
P.O. Box 718
Gresham, OR 97030-0172
(704)450-9934
angela@blackwelldevice.com

Device Description: The XOD diathermia radiofrequency device generates high frequency sinusoidal current with a monopolar mode of application using two electrodes. A fixed electrode is placed in contact with the patient and a handheld electrode is manipulated by a therapist. When both electrodes are in contact with a patient the electrical circuit is closed, and RF therapy can be provided. The device can be operated in a resistive monopolar mode.
The product consists of a portable power console with a color touchscreen, and accessories including resistive threaded electrodes, and a silicon return plate. The unit can be adjusted to provide various levels of treatment frequency ranging from 442kHz to 454MHz.

Indications for Use: The XOD diathermia radiofrequency device is intended to provide topical heating for the purpose of elevating tissue temperature for the treatment of selected medical conditions such as relief of pain, muscle spasms, and increase in local circulation. The XOD device also is intended to provide a temporary reduction in the appearance of cellulite.

Testing Summary: EMC testing shows the device meets IEC 60601-1-2. Electrical safety testing shows the device meets IEC 60601-1 and IEC 60601-1-6. The device components which contact the patient or the user were evaluated according to ISO 10993-1. Performance testing shows the device meets the design specifications.

Predicate Devices: K161458 Indiba Diathermia Radiofrequency Device

Substantial Equivalence:

XOD's diathermia radiofrequency device is substantially equivalent to Indiba's because they have the same indications, device description, the same principle of operation and similar operating parameters.

	XOD Diathermia Radiofrequency Device	Indiba Diathermia Radiofrequency Device K161458 Predicate Device
Product Code	PBX	PBX
Indications for Use	The XOD diathermia radiofrequency device is intended to provide topical heating for the purpose of elevating tissue temperature for the treatment of selected medical conditions such as relief of pain, muscle spasms, and increase in local circulation. The XOD device also is intended to provide a temporary reduction in the appearance of cellulite.	The Indiba Diathermia Radiofrequency Devices are intended to provide topical heating for the purpose of elevating tissue temperature for treatment of selected medical conditions such as: relief of pain, muscle spasms, increase in local circulation. The massage device provided is intended to provide a temporary reduction in the appearance of cellulite.
Device Description	The XOD diathermia radiofrequency device generates high frequency sinusoidal current with a monopolar mode	The Indiba Diathermia Radiofrequency Device is a therapeutic device for deep, non-invasive diathermy. The

	of application using two electrodes. A fixed electrode is placed in contact with the patient and a handheld electrode is manipulated by a therapist. When both electrodes are in contact with a patient the electrical circuit is closed, and RF therapy can be provided. The device can be operated in a resistive monopolar mode. The product consists of a portable power console with a color touchscreen, and accessories including resistive threaded electrodes, and a silicon return plate. The unit can be adjusted to provide various levels of treatment frequency ranging from 442kHz to 454MHz.	device consists of a console which generates a radiofrequency current which is delivered to the patient, in monopolar form, through two different types of electrodes: stainless steel conductive resistive electrodes, and thin-layer insulated capacitive electrodes. The electrodes are inserted into a handle/handpiece, one handle for each kind of electrode, and the handle is connected to the console by means of a 2-metre cable. In resistive mode the system delivers a high-frequency current of 448 kHz directly to the patient's skin surface. In capacitive mode, the electrode coating creates a layer between the electrode and the human tissue, forming a capacitor that allows a high-frequency current to pass.

		The high frequency current ranges between 400 kHz and 449 kHz and is automatically tuned by the equipment according to the patient's impedance. Current returns through the neutral return electrode. The Indiba Diathermia Radiofrequency Device is provided with an electroconductive media which is applied to the patients' skin prior to each treatment session. The RF energy generates a heating profile that produces a moderate temperature rise in the subcutaneous tissue. The temperature on the skin is measured using a separate IR (Infra-red) thermometer and there is an integrated massage device that can be used to

		massage the skin during cellulite treatment.
Principle of Operation	Uses radiofrequency to raise tissue temperature	Uses radiofrequency to raise tissue temperature
Frequency Range	442-454kHz	400-449kHz
Input Voltage Supply	(100-240) V~ 50/60 Hz Max RF Power 350W	(100 – 130) V~ 50/60 Hz Max RF Power 200W
Time of Treatment	20-30 minutes	0-99 minutes
Intensity of Treatment	0-100%	0-100%
Maximum Temperature Range for Tissue	40-45°C	40-45°C
Electrical Safety Testing Meets IEC 60601-1 and IEC 60601-1-6	Yes	Yes for only IEC 60601-1
EMC Testing Meets IEC 60601-1-2	Yes	Yes
Biocompatibility Assessment According to ISO 10993	Yes	Yes
Type of Electrodes and Return plates	resistive threaded electrodes silicon return plate	resistive electrodes capacitive electrodes neutral plate

Conclusion:

The XOD Diathermia Radiofrequency Device has the similar indications (the same as those of the predicate device other than details of parts of the device) to the predicate device, the same temperature range and frequency range as the predicate device, the same type of electrodes as the predicate device, and a similar input voltage supply to the predicate device and testing to the same standards as the predicate device. Any differences are due to the physical differences of the devices due to size (portable device versus a device on a cart) but do not impact the substantial equivalence in any way.