July 15, 2024

Zimmer MedizinSysteme GmbH
% Scott Blood
Principal Consultant
QARA Consulting
151 Gleasondale Road
Stow, Massachusetts 01775

Re: K240178
Trade/Device Name: RFG-01
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: PBX
Dated: January 19, 2024
Received: January 23, 2024

Dear Scott Blood:

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.

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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2024.07.15 11:02:03 -04'00'

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

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)*

K240178

Device Name

RFG-01

Indications for Use *(Describe)*

The RFG-01 is intended to:
- provide topical heating for the purpose of elevating tissue temperature for the treatment of selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation.
- provide, with a massage device, 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.

510(k) Summary
RFG-01
K240178

1. **Basic Information-Submitter**:

510(k) Owner:	Zimmer MedizinSysteme GmbH Junkersstrasse 9 89231 Neu-Ulm Germany Establishment Registration: 8010720
	Ms. Ute Killet Manager Regulatory Affairs Phone: +49-7319761-216 Fax: +49-731-9761-118 E-Mail: u.killet@zimmer.de
Official Contact:	Mr. Scott Blood Principal Consultant Phone: 978.729.5978 Fax: +49-731-9761-118 E-mail: scottqara@gmail.com
Date Summary Prepared:	January 19, 2024

2. **Device Name**:

Trade Name:	RFG-01
Common Name:	Electrosurgical cutting and coagulation device and accessories
Classification Name:	Massager, Vacuum, Radio Frequency Induced Heat
Regulation Number:	21 CFR 878.4400
Product Code:	PBX
Classification:	Class II

3. **Predicate Device**: NuEra Tight RF Family – K200359
Company Name: Bios s.r.l.

Reference Device: Venus Legacy Pro Device – K191528
Company Name: Venus Concept USA Inc.

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4. **Device Description**:

The RFG-01 is a mobile standalone equipment with four wheels and consists of a console (main unit), a color display with touch operation and three handpieces (small, medium, and large).

The device develops localized heat to warm the subcutaneous tissue by means of radio frequency energy, delivered through electrodes in contact with the patient. The purpose of the treatment based on the radiofrequency system is to raise the temperature inside the tissues up to maximum of 45°C. Therefore, depending on the treatment and intended use, different parts of the body can be treated. The devices use RF electrodes of the resistive (or bipolar) types. Resistive RF electrodes have different sizes and plug into an RF handpiece that provides connection to the RF generator (through the electrode connectors). Handpieces of different shapes are available to facilitate use by the operator on different body parts. The use of different sizes allows efficient and effective treatment of various parts of the body. Two of the three handpieces can be used with or without vacuum, allowing an even deeper application of heat. The handpieces are to be used with a small amount of contact lotion, the purpose of which is to assist in heat transfer. The LEDs on every handpiece indicate the coupling and the correct temperature range during the treatment. The color touchscreen displays all treatment-related parameters.

5. Indications for Use Statement:

The RFG-01 is intended for:

- to provide topical heating for the purpose of elevating tissue temperature for the treatment of selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation.
- to provide, with a massage device, a temporary reduction in the appearance of cellulite.

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ATTRIBUTE	SUBJECT DEVICE Zimmer MedizinSysteme GmbH RFG-01 **This Submission**	PREDICATE DEVICE Bios s.r.l. NuEra Tight RF Family K200359	REFERENCE DEVICE Venus Concept USA Inc. Venus Legacy Pro Device K191528
Product Code and Regulation	General & Plastic Surgery 21 CFR 878.4400 PBX – Massager, Vacuum, Radio Frequency Induced Heat	General & Plastic Surgery 21 CFR 878.4400 PBX – Massager, Vacuum, Radio Frequency Induced Heat	General & Plastic Surgery 21 CFR 878.4400 GEI – Electrosurgical, Cutting & Coagulation & Accessories PBX – Massager, Vacuum, Radio Frequency Induced Heat
Indications for Use	The RFG-01 is intended for: - to provide topical heating for the purpose of elevating tissue temperature for the treatment of selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation. - to provide, with a massage device, a temporary reduction in the appearance of cellulite.	The NuEra Tight FR Family is intended for: - to provide topical heating for the purpose of elevating tissue temperature for the treatment of selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation. - to provide, with a massage device, a temporary reduction in the appearance of cellulite.	When used with the Octipolar (LB1) or Diamondpolar (LF1) applicators, the Venus Legacy Pro device is intended for use in dermatologic and general surgical procedures for females for the non-invasive treatment of moderate to severe facial wrinkles and rhytides in Fitzpatrick skin types I-IV. When used with the 4D Body (LB2) or 4D Face (LF2) applicators, the Venus Legacy Pro device is intended for the delivery of non-thermal RF combined with Massage and magnetic field pulses for the treatment of the following medical conditions: • Relief of minor muscles aches and pain, relief of muscle spasm • Temporary improvement of local blood circulation • Temporary reduction in the appearance of cellulite

The Indications for Use statement of RFG-01 is identical to the predicate device NuEra Tight RF Family.

6. **Technological Characteristics**:

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Technological Characteristics	**SUBJECT DEVICE** Zimmer MedizinSysteme GmbH RFG-01 **This Submission**	**PREDICATE DEVICE** Bios s.r.l. NuEra Tight RF Family K200359	**REFERENCE DEVICE** Venus Concept USA Inc. Venus Legacy Pro Device K191528
Principle of action	Electromagnetic waves penetrate in exposed tissue and produce heat, increasing the temperature on a certain part of the body for therapeutic purposes.	Electromagnetic waves penetrate in exposed tissue and produce heat, increasing the temperature on a certain part of the body for therapeutic purposes.	Electromagnetic waves penetrate in exposed tissue and produce heat, increasing the temperature on a certain part of the body for therapeutic purposes.
Clinical Use	Prescription Use	Prescription Use	Prescription Use
Electrical Protection	Class I Type BF	Class I Type BF	unknown
User Interface	Touch Screen	Touch Screen	unknown
Firmware controlled	Yes	Yes	Yes
Type of Energy	Radiofrequency waves and Vacuum	Radiofrequency waves	RF Energy 2. Pulsed Magnetic Field (PMF) 3. Vacuum
Temperature Control	Yes	Yes	Yes
Frequency	1 MHz, 2 MHz, 4 MHz	470 kHz; 1 MHz; 2 MHz; 4 MHz; 6 MHz	1 MHz
Output RF Power	Small handpiece: Max 30W Medium handpiece: Max 46W Large handpiece: Max 88W	Max 250W	Maximal RF output power for each applicator - Octipolar (LB1), Diamondpolar (LF1), 4D Body (LB2) and 4D Face (LF2): up to 150W
Power Requirements	110 - 240V ~ 50/60Hz	100 – 240 V	100-120 VAC / 60Hz 220-240 VAC / 50Hz
Vacuum pressure handpieces	<u>Small handpiece</u> Unavailable <u>Medium handpiece</u> Continuous and Pulse1-3: 0~300mmHg <u>Large handpiece</u> Continuous and Pulse1: 0~270mmHg Pule 2 and Pulse 3: 0~300mmHg	unavailable	-400mbar
Materials	Materials are biocompatible	Materials are biocompatible	Materials are biocompatible

There are only a few technological differences between the subject device, the predicate and reference device. Those differences are discussed below and do not affect or raise any new types of safety or performance questions.

The Zimmer MedizinSysteme GmbH subject device RFG-01 has the same technological characteristics as the predicate and the reference device except of the following:

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Characteristic difference between subject device RFG-1, predicate device NuEra Tight RF Family and the reference device Venus Legacy Pro Device		
Technological Characteristics	**Difference in Characteristics**	**Discussion on why this difference does not affect the overall safety and effectiveness of the subject device when compared to the predicate device and the reference device**
Type of Energy	Subject: Radiofrequency waves and Vacuum Predicate: Radiofrequency waves Reference: 1. RF Energy 2. Pulsed Magnetic Field (PMF) 3. Vacuum	The medium and large handpieces of the subject device can be used with or without vacuum as well as the reference device. A treatment with vacuum allows an even deeper application with heat.
Frequency	Subject: 1 MHz, 2 MHz, 4 MHz Predicate: 470 kHz; 1 MHz; 2 MHz; 4 MHz; 6 MHz Reference: 1 MHz	For the radiofrequency function, the only difference is that the predicate device (K200359) works at additional frequencies of 470kHz and 6MHz, the reference device (K191528) works only at a single frequency of 1MHz. The subject device works at multiple frequencies as the predicate device and includes the single frequency of the reference device.
Output RF Power	Subject: Small handpiece: Max 30.0W Medium handpiece: Max 46W Large handpiece: Max 88W Predicate: 250W maximum Reference: 150W maximum	Even with less power, the effectiveness of treatment is guaranteed. The safety of the application is even increased due to less power. Since the required temperature is reached even with reduced power and the risk of burns due to excessive temperatures is minimized.
Power Requirements	Subject: 110 - 220V, ~50/60Hz Predicate: 100 - 240V Reference: 100-120 VAC / 60Hz 220-240 VAC / 50Hz	No impact. The energy source is sufficient to operate the device under normal operating conditions.

Characteristic difference between subject device RFG-1, predicate device NuEra Tight RF Family and the reference device Venus Legacy Pro Device		
Technological Characteristics	**Difference in Characteristics**	**Discussion on why this difference does not affect the overall safety and effectiveness of the subject device when compared to the predicate device and the reference device**
Vacuum pressure handpieces	Subject: Medium handpiece Continuous and Pulse1-3: 0~300mmHg Large handpiece Continuous and Pulse1: 0~270mmHg Pule 2 and Pulse 3: 0~300mmHg Predicate: unavailable Reference: -400mbar	The maximum vacuum pressure of the subject device and the reference device is the same (400mbar = 300mmHg)

7. Performance data

The technological characteristics of the RFG-01 device has been verified based on assessments of electrical safety, performance testing, biocompatibility and usability.

The following testing has been conducted with satisfactory results:

- Usability & Risk Management: Usability and Risk Management assessments were done using worst-case assumptions to verify user interface, safety features and satisfactory performance.
- RF Power Accuracy
- Vacuum Pressure Accuracy
- Thermal Effect on Skin testing

The following consensus standards were used in the development of this device:

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Standards	Standards Organization	Standards Title
60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION	IEC	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
60601-1-2 Edition 4.1 2020-09	IEC	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
60601-1-6 Edition 3.1 2013-10	IEC	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
60601-2-2 Edition 6.0 2017-03	IEC	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
62304 Edition 1.1 2015-06	IEC	Medical devices software –software life cycle processes
62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION	IEC	Medical devices – Part 1: Application of usability engineering to medical devices
10993-1 Fifth Edition 2018-08	ISO	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
10993-5 Third Edition 2009-06-01	ISO	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
10993-10 Third Edition 2010-08-01	ISO	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
10993-18 Second Edition 2020-01	ISO	Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process
10993-23 Frist Edition 2021-01	ISO	Biological evaluation of medical devises – Part 23: Tests for irritation
14971 Third Edition 2019-12	ISO	Medical devices – Application of risk management to medical devices

The following table shows a comparison of the performance testing in comparison to the predicate device and the reference device:

Standards	**SUBJECT DEVICE** Zimmer MedizinSysteme GmbH RFG-01 **This Submission**	**PREDICATE DEVICE** Bios s.r.l. NuEra Tight RF Family **K200359**	**REFERENCE DEVICE** Venus Concept USA Inc. Venus Legacy Pro Device **K191528**
ANSI/AAMI ES60601-1	X	X	X
IEC 60601-1-2	X	X	X
IEC 60601-1-6	X	X	X
IEC 60601-2-2	X	X	X
IEC 62304	X	X	X
IEC 62366-1	X	unknown	unknown
ISO 14971	X	unknown	unknown
ISO 10993-1 ISO 10993-5 ISO 10933-10 ISO 10933-18 ISO 10933-23	X X X X X	X X X unknown unknown	unknown unknown unknown unknown unknown

According to this comparison table all required performance tests were conducted and show substantial equivalence with the predicate device and the reference device.

8. Conclusion:

Zimmer MedizinSysteme GmbH has demonstrated that the RFG-01 device is substantially equivalent to the predicate device.