June 6, 2022

Globus Sport and Health Technologies LLC
% Jorge Millan, Ph.D.
Regulatory Consultant
Sigma Biomedical
7737 N University Drive, Suite 101
Tamarac, Florida 33321

Re: K211207
Trade/Device Name: Diacare 7000
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: PBX
Dated: May 2, 2022
Received: May 9, 2022

Dear Dr. Millan:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211207

Device Name
Diacare 7000

Indications for Use *(Describe)*
The Diacare 7000 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.

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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510(K) Summary

Submitter Information

Submitter	Ruben Curbello General Manager Globus Sport and Health Technologies 7280 NW 7th St # 109, Miami, Florida 33126
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Date prepared:	June 3, 2022

Subject Device Name

Trade/Proprietary Name:	Diacare 7000
Regulation Number:	878.4400
Product Code:	PBX
Class	II
Panel	Physical Medicine

Predicate Device

Predicate Device:	Winback 3SE cleared under K162828
Regulation Number:	878.4400
Product Code:	PBX
Class	II
Panel	Physical Medicine

Device Description

The Diacare 7000 is a diathermy device that generates a high frequency sinusoidal current with a monopolar and bipolar mode of application using two electrodes. A fixed electrode is placed in contact with the patient and a hand-held electrode is manipulated by a therapist. When the electrode is in contact with a patient the electrical circuit is closed and RF therapy can be provided. The device can be operated in capacitive and resistive monopolar modes. The Diacare 7000 consists of a power console on LCD monitor, and accessories including capacitive and resistive bipolar and monopolar electrodes. The unit can be adjusted to provide various levels of treatment frequency ranging from 400 KHz to 1.2 MHz.

Indications for Use

The Diacare 7000 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.

Predicate Device

Primary predicate: Winback 3SE cleared under K162828

Comparison with the Predicate Devices [21 CFR 807.92(a) (6)]: Diacare 7000 is comparable with and substantially equivalent to the Winback 3SE device.

Technical Characteristics Comparison:

The basic and main technical features of the subject device are the same as the predicated device

Feature Comparison:

Subject device has similar features and functionality as the predicate device:

Product comparison

Element of Comparison	New Device:	Predicate Device:	Similarities or Differences
	Diacare 7000	Winback Back 3SE	
K#	K211207	K162828	
Regulation and Product Classification Code	21 CFR 878.4400 PBX	21 CFR 878.4400 PBX	Same
Regulatory Class	II	II	Same
Product Code	PBX	PBX	Same
Indications for Use	The Diacare 7000 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 Winback Back 3SE 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 Winback 3SE massage device is intended to provide a temporary reduction in the appearance of cellulite.	Similar
Tissue treated	Superficial, semi deep, and deep	Superficial, semi deep, and deep	Same
Operating Principle	Diathermy Application on a biological tissue of an electromagnetic field with proper power, frequency and wave length increases tissue temperature	Diathermy Application on a biological tissue of an electromagnetic field with proper power, frequency and wave length increases tissue temperature	Same
Electrode Shapes	Square and circular	Square and circular	Same
Infrared Light	No	No	Same
Vacuum (suction)	No	No	Same
Treatment Activation	Finger selection on console	Finger selection on console	Same
RF Type	Bipolar/Unipolar	Multipolar/Unipolar	Similar
RF Frequency	400kHz, 470kHz, 700kHz, 1000 kHz, 1200 kHz	300KHz – 1 MHz	Diacare can operate at 1.2 MHz

Max RF Power	250 W	300 W	Diacare 7000 has less power consumption
Intensity Adjustment	0-100%	0-100%	Same
Configuration	Console	Cart mounted console with accessories	Diacare 7000 is portable and does not require a cart
Display	LCD Display	LCD Display	Same
Patient Safety Switch	Yes	Yes	Similar
Standards Compliance	ISO10993, IEC60601-1, IEC60601-1-2 & IEC60601-2-3 Compliant	ISO10993, IEC60601-1 & IEC60601-1-2 Compliant	Similar
Tissue temperature elevation performance	Capable	Capable	Similar

Evaluation of similarities and differences:

- The Diacare 7000 and the Winback 3SE have similar intended use, operating principle, functionality and similar technologies and ranges of operation. The DIACARE 7000 has demonstrated equivalent safety and effectiveness as shown in the safety and performance test reports.
- Differences between both systems consist in user interface layout, navigation, icon coloring and overall system presentation. The Diacare 7000 can operate with RF frequencies of 1.2 MHz. This frequency is in the range of other diathermy devices, which can operate up to 27 MHz, and does not raise issues of safety or effectiveness.

Non-Clinical Data and Performance Testing

Non-clinical product evaluation to demonstrate safety and effectiveness was conducted. Non-clinical testing includes:

- Risk Management: Software Usability and Risk Analysis were done using worse-case assumptions to verify user interface, safety features and satisfactory performance.
- Electrical Safety Testing IEC 60601-1:2005 + A1:2012 and EN 60601-1:2006 + A2:2013 to demonstrate electrical safety of the device.
- Electromagnetic Compatibility IEC 60601-1-2:2015 to demonstrate the device does not interfere or interact with surrounding electromagnetic equipment.

- Electrical Safety of short-wave therapy equipment IEC 60601-2-3:2012 and EN 60601-2-3: 2015.
- Biocompatibility: Biocompatibility analysis of the patient contact materials was conducted for biosafety. The conductive cream has previously received market clearance.
- Tissue Temperature Elevation Assessment: Studies were performed using volunteers of varying skin colors to assess the capacity of the device to elevate tissue temperature in the treatment areas. Results indicated satisfactory safe therapeutic increases in tissue temperature.
- Software verification and validation testing were conducted on the Diacare 7000 system 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 flaw in the software would lead to a delayed delivery of appropriate medical care. Documentation includes level of concern, software requirements and specifications, design architecture, risk analysis and software validation and verification.

Conclusion

The subject device has similar technology characteristics and has the similar intended use and functionality as legally marketed devices. There are no differences between the devices that affect the usage, safety and effectiveness, thus no new question is raised regarding the safety and effectiveness. In accordance with the 21 CFR Part 807 and based on the information provided in this premarket notification, Diacare 7000 is substantially equivalent to the predicate device with regards to safety and effectiveness.