December 26, 2024

Golden Star Srl
Tiziana Borrelli
Product Manager
Via Enrico Pallini 9
Roma, 00149
Italy

Re: K232966
Trade/Device Name: Fisiowarm 7.0
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: PBX
Dated: September 18, 2024
Received: November 27, 2024

Dear Tiziana Borrelli:

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,

Francisco Delgado -S
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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)*

K232966

Device Name

FISIOWARM 7.0 (FISIOWARM 7.0)

Indications for Use *(Describe)*

FISIOWARM® 7.0 300 and FISIOWARM® 7.0 400 are 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 massage devices are 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.

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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SECTION 5

510 (k) SUMMARY

510 (k) SUMMARY

SUBMITTER INFORMATION

A. Company Name:	GOLDEN STAR S.r.l.
B. Company Address:	Via Enrico Pallini 9 00149 Roma (RM) - Italy
C. Company Phone: Company e-mail:	+39 06 5897627 amministrazione@goldenstar.it
D. Contact person:	Stefano Giordano CEO Golden Star S.r.l.
E. Date Summary Prepared:	18th September 2023

DEVICE IDENTIFICATION

A. Device Name:	FISIOWARM 7.0 300 & FISIOWARM 7.0 400
B. Common Name:	Electrosurgical, Cutting & Coagulation & Accessories
C. Classification:	Class II
D. Product Code:	PBX
E. Regulation Number:	878.4400
E. Submission Type:	510k (Original Submission)

LEGALLY MARKETED PREDICATE DEVICE

Primary predicate device	510 (k) Holder	510 (k) No.	Date cleared
Winback Back 3SE	**WINBACK USA Corp**	K162828	September 18th, 2017

DEVICE DESCRIPTION

FISIOWARM® 7.0 300 and FISIOWARM® 7.0 400 are active and therapeutic medical devices that perform their function by releasing energy to the human body.

Performance Testing

The following performance testing was conducted to prove compliance with performance requirements and support substantial equivalence:

Test	Objective	Result
Electrical	Compliance with EN 60601-1	Pass
	Compliance with EN 60601-1-2	Pass
Tissue Testing	Compare thermal spread of devices	Equivalent

INDICATIONS FOR USE STATEMENT

FISIOWARM® 7.0 300 and FISIOWARM® 7.0 400 are 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 massage devices are intended to provide a temporary reduction in the appearance of cellulite.

SUBSTANTIAL EQUIVALENCE

All information provided with the present submission supports the substantial equivalence for FISIOWARM® 7.0 300 and FISIOWARM® 7.0 400 with the predicate device and its accessories that have identical characteristics and intended use and similar indication statement. In addition all clinical data and all performance tests that have been performed in accordance with the Standards for the Software Evaluation and for the Electrical and Electromagnetic Safety test, demonstrate FISIOWARM® 7.0 300 and FISIOWARM® 7.0 400 safety and effectiveness for its intended use.

The following matrix illustrates the equivalencies of FISIOWARM® 7.0 300 and FISIOWARM® 7.0 400, as well as the substantial equivalent predicate device.

PREDICATE DEVICES COMPARISON CHART

Table 1

	GOLDENSTAR S.r.l. FISIOWARM 7.0 300 FISIOWARM 7.0 400 New Device	**WINBACK USA Corp Winback Back 3SE** Predicate device
"K" NUMBERS	**K232966**	**K162828**
Proprietary name	**FISIOWARM 7.0 300** **FISIOWARM 7.0 400**	**Winback Back 3SE**
CFR Section	878.4400	878.4400
Pro-code	PBX	PBX
Intended / Indications for use	FISIOWARM® 7.0 300 and FISIOWARM® 7.0 400 are 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 massage devices are intended to provide a temporary reduction in the appearance of cellulite.	The Winback Back 3SE 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 massage devices are intended to provide a temporary reduction in the appearance of cellulite.
Mode of operation	Radiofrequency energy	Radiofrequency energy
Output	Unipolar/Bipolar/Multifunction*	Unipolar/Multipolar
Power Supply	100-240VAC 50/60Hz	110-250 VAC 50/60 Hz
Frequency	300kHz – 1 MHz	300kHz – 1 MHz
Max RF Power	300W – 400W**	300W
Configuration	Console with accessories	Cart mounted console with accessories
Electrical Safety Standards	Complies with IEC60601-1, IEC60601-1-2, IEC60601-2-2	Complies with IEC60601-1, IEC60601-1-2, IEC60601-2-2
Handpieces	Resistive, capacitive	Resistive, capacitive
Electrodes	Resistive, capacitive, neutral, dermato-functional, static automatic, neutral dynamic	Resistive, capacitive, neutral, dermato-functional, static automatic, neutral dynamic

* Bipolar and Multifunction Outputs are the Multipolar Output splitted in two separated connectors.

** The Fisiowarm 400 can handle 30% more power for very demanding and intensive usage.

TECHNICAL CHARACTERISTICS

A comparison of the technological characteristics of FISIOWARM® 7.0 300 and FISIOWARM® 7.0 400 and the predicate device has been performed. The results of this comparison demonstrate that the technologic characteristics and the operating principle of FISIOWARM® 7.0 300 and FISIOWARM® 7.0 400 are the same or very similar to those of the claimed predicate device. Where any differences arise from the analysis of the predicate device characteristics and those of the device subject of this submission, the clinical data evaluated from scientific publications give scientific evidence of the safety and the effectiveness of FISIOWARM® 7.0 300 and FISIOWARM® 7.0 400. The system was evaluated and found compliant with IEC 60601-1 for electrical safety, IEC 60601-1-2 for electromagnetic compatibility, and ISO 10993-1 for biocompatibility of the handpieces and electrodes. Verification and validation data show that the device meets all product specifications.

PERFORMANCE DATA

Laboratory and performance tests were executed to ensure that the device functioned as intended and met design specifications. A comparative thermal test was performed on human skin in order to experimentally verify the transfer of energy to the biological tissue of both devices. This verification was carried out by measuring the trend of the temperature increase in the biological tissue over time, at different energy levels.
Sufficient data were obtained to show that the device is substantially equivalent to the predicate device and meets safety and effectiveness criteria.

CLINICAL DATA

The devices have been designed and validated in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or other people, provided that any risk which may be associated with its use constitute acceptable risks when weighed against the benefits to the patient and is compatible with a high level of protection of health and safety.

CONCLUSION

Based on the foregoing, FISIOWARM® 7.0 300 and FISIOWARM® 7.0 400 are substantially equivalent to the legally marketed, claimed predicate devices for the purposes of this 510(k) submission. Safety and effectiveness were reasonably assured, justifying 510 (k) clearance.