October 18, 2024

Fabinject lndustria e Comercio lmportacao e Exportacao Ltda
% Aleksandro Gardano
Principal Consultant, Regulatory Affairs
Regulab
34 Pinar del Rio Avenue
Brownsville, Texas 78526

Re: K242132
Trade/Device Name: FREDDO
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
Dated: July 2, 2024
Received: July 22, 2024

Dear Aleksandro Gardano:

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,

TANISHA L. HITHE -S

Digitally signed by TANISHA L. HITHE -S
Date: 2024.10.18 16:59:22 -04'00'

Tanisha Hithe
Assistant Director
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K242132

Device Name
Freddo

Indications for Use *(Describe)*
The Freddo is indicated to be used to:

Minimize pain and thermal injury during laser and dermatological treatments and for temporary topical anesthetic relief for injections.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92.

I. SUBMITTER:

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DATE PREPARED: October 17, 2024

II. DEVICE:

TRADE NAME: Freddo

COMMON NAME: Laser surgical instrument for use in general and plastic surgery and in dermatology

CLASSIFICATION NAME: Powered Laser Surgical

Instrument DEVICE CLASSIFICATION: Class II, 21 CFR

§878.4810 PRODUCT CODE: GEX

III. PREDICATE DEVICE: Cryo V6.0 (K060395)

IV. DEVICE DESCRIPTION:

The Freddo is a non-invasive therapeutic device. The cold air therapy device cools and dehumidifies the air, which can be used to minimize pain and thermal injury during laser and dermatological treatments and for temporary topical anesthetic relief for injections. The cold air therapy device is intended to cool the patient's skin locally and is intended to be used contactless. The subject Freddo device is substantially equivalent as the currently cleared Cryo 6 (K060395).

The mechanical assembling consists of a housing, a chassis with 4 rotating rollers and a shelf plate. The chassis includes all technical components, like compressor, evaporator, condenser, fans, and all electrical power components. On the upper front cover, the user interface control it operated via membrane keyboard.

The software controls the device initialization, the hardware components for the cooling circuit as well as the user interface. The user interface can be controlled via membrane keyboard. The software controls the device initialization, the hardware components for the cooling circuit as well as the user interface.

V. INDICATONS FOR USE:

Freddo is indicated to be used to:

Minimize pain and thermal injury during laser and dermatological treatments and for temporary topical anesthetic relief for injections.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

The technological characteristics and operating principle associated with the treatment of Freddo delivers remain unchanged from the predicate device. The device produces cold air for blowing on patient's skin locally and is intended to be contactless.

The technological similarities and differences between the subject device (Freddo) and the predicate device (Zimmer Cryo-6) are described below in the comparison table. The differences do not raise any new questions regarding safety or effectiveness.

Comparison with the Predicate Device	**SUBJECT DEVICE** **Fabinject Ind Com Imp Exp Ltda** **Freddo (This Submission)**	**PREDICATE DEVICE** **Zimmer MedizinSysteme GmbH** **Cryo V6.0 (K060395)**	**Discussion**
Product Code and Regulation	General & Plastic Surgery 21 CFR 878.4810 GEX – Powered Laser Surgical Instrument	General & Plastic Surgery 21 CFR 878.4810 GEX – Powered Laser Surgical Instrument	Identical
Device Description	The Freddo Cold Air Device utilizes a compressor, evaporator, and fan to cool the patient's skin locally and contactless.	The Zimmer Cryo V6.0 Cold Air Device utilizes a compressor, evaporator and fan to cool room air and then direct it onto skin.	Identical
Intended Use	The Freddo is intended to minimize pain and thermal injury during laser and dermatological treatments and for temporary topical anesthetic relief for injections.	The Cryo V6.0 Cold Air Device is intended to minimize pain and thermal injury during laser and dermatological treatments and for temporary topical anesthetic relief for injections.	Identical
Performance Characteristics Measurement at device outlet	-17°C to -28°C (± 3°C) At an air speed of 160 to 780 liters/minute (± 10%).	-31°C At an air speed of 100 to 1000 liters/minute.	Similar, not significantly different
Cooling Method, Operation principle	Cooling agent-based condenser and evaporation system. Cold air is produced which is then directed onto the skin. Conduction, evaporation, and forced convection cool the skin.	Cooling agent-based condenser and evaporation system. Cold air is produced which is then directed onto the skin. Conduction, evaporation, and forced convection cool the skin.	Identical
Cooling Material	Gas (Air)	Gas (Air)	Identical
Mains Voltage	120V / 60Hz	100V – 120V / 50-60Hz	Similar, not important for the device safety and effectiveness evaluation
Main Fuse	16A circuit breaker in main switch for 120V 10A circuit breaker in main switch for 220V	16A circuit breaker in main switch	Similar, not important for the device safety and effectiveness evaluation
Power Consumption	Max. 11A	Max. 9 - 11A	No impact
IP classification	IPX0	IPX0	Identical
Design	Metal enclosure	Metal enclosure	Identical
Materials	Environmentally approved R404, closed loop cooling system	Environmentally approved R507, closed loop cooling system	Both environmentally approved, no impact
Cooling spot Size	Varies with distance from distal end of air hose to tissue – 10cm² @ 5cm distance	Varies with distance from distal end of air hose to tissue – 10cm² @ 5cm distance	Identical
Fan speed settings	1 - 3	1 - 9	No impact

Comparison with the Predicate Device	**SUBJECT DEVICE** **Fabinject Ind Com Imp Exp Ltda** **Freddo (This Submission)**	**PREDICATE DEVICE** **Zimmer MedizinSysteme GmbH** **Cryo V6.0 (K060395)**	**Discussion**
Interface	N/A	N/A	Identical
Therapy time, treatment time	15:00 – 90:00 min timer – user selectable	1-99 minute timer – user selectable	Similar, not significantly different
Time delay to operate	Immediate from pressing start button once unit achieves standby mode	Immediate from pressing start button once unit achieves standby mode	Identical
Compatibility with the environment	R404 Ozone destruction level 0	R507 Ozone destruction level 0	Both environmentally approved, no impact
Display	LCD display	LCD display	Identical
Weight without accessories	55 kg	60 kg	No impact
Dimensions	H 710 mm x W 480 mm x D 510 mm	H 645 mm x W 390 mm x D 680 mm	Different dimensions have no influence on the device safety and effectiveness evaluation
Operating Ambient Temperature and Humidity	Temperature: 10 - 35°C Humidity: 20-80% relative humidity without condensation Air pressure: 900-1060 hPa	Temperature: 10 - 35°C Humidity: 20-80% relative humidity without condensation Air pressure: 900-1060 hPa	Identical
Storage and Transport	Storage: Temperature: 0 - 40°C Humidity: 10-90% relative humidity without condensation Air pressure: 600-1060 hPa Transport: Temperature: -10 - 50°C Humidity: 10-90% relative humidity without condensation Air pressure:600-1060 hPa	Storage: Temperature: 0 - 40°C Humidity: 10-90% relative humidity without condensation Air pressure: 600-1060 hPa Transport: Temperature: -10 - 50°C Humidity: 10-90% relative humidity without condensation Air pressure:600-1060 hPa	Identical
Environmental Specifications	For indoor use only	For indoor use only	Identical

VII. PERFORMANCE DATA:

The Freddo has been investigated and tested against and complies with the following recognized standards:

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 CONSOLIDATED VERSION	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 3.2 2020-07 CONSOLIDATED VERSION	IEC	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION	IEC	Medical devices – Part 1: Application of usability engineering to medical devices
62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	IEC	Medical devices software –software life cycle processes
14971 Third Edition 2019-12	ISO	Medical devices – Application of risk management to medical devices
15223-1 Fourth edition 2021-07	ISO	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements
10993-1 Fifth edition 2018-08	ISO	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

Software Verification and Validation Testing

After evaluation of the specified use conditions, it could be demonstrated that the technical design including software flow and device usage of the Freddo is suitable to fulfill the specified intended use. In both formative and summative testing performed, no application problems were identified that could lead to any risk for the user, patient or third.

The verification of the software requirements was performed according IEC 62304. All the tests were performed successfully and met their acceptance criteria.

Biocompatibility Testing

The device has been assessed for the requirement of biocompatibility testing per ISO 10993-1. Since the device is not intended to contact the patient and the user contacts the device only through gloved hands, there are no additional biocompatibility requirements for the device.

Electrical safety and electromagnetic compatibility (EMC)

The device has undergone electrical and mechanical safety performance testing and electromagnetic compatibility testing. The system complies 60601-1 Edition 3.2 and 60601-1-2 Edition 4.1.

VIII. CONCLUSION:

The proposed indications for use for the Freddo are the same as those cleared in K060395. The subject device described in this submission is essentially the same device cleared in K060395. The Freddo device has the same intended use as the predicate and do not imply new technological characteristics.
According to the Risk-Benefit analysis, the global residual risk has been deemed acceptable since it falls in the area between negligible risks and acceptable risks.

The Freddo is substantially equivalent to the predicate device.