February 4, 2022

Zimmer MedizinSysteme GmbH
% Scott Blood
Principal Consultant
Quality and Regulatory Services
151 Gleasondale Road
Stow, Massachusetts 01775

Re: K220020
Trade/Device Name: Cryo 7
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: December 29, 2021
Received: January 5, 2022

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 (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,

Purva Pandya
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)*
K220020

Device Name
Cryo 7

Indications for Use *(Describe)*
The Cryo 7 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.

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Zimmer MedizinSysteme

510(k) SUMMARY

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

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DATE PREPARED: December 29, 2021

II. DEVICE:

TRADE NAME: Cryo 7

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 Cryo 7 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 Cryo 7 device is the same as the currently-cleared Cryo 6

(K060395), except for branding and state-of-the-art updates. Both the subject device and predicate device are manufactured by Zimmer MedizinSysteme GmbH.

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 touchscreen.

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 capacitive touch display. The software controls the device initialization, the hardware components for the cooling circuit as well as the user interface.

V. INDICATONS FOR USE:

Cryo 7 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 this device 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.

Updates were made to the predicate device (K060395) system hardware, mechanical layout and the display (new, 10.1 inch touch display). Also, the software was adapted according to the hardware modifications. Specifically, the cooling parameters remain unchanged.

The technological similarities and differences between the subject device and the predicate device 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 Zimmer MedizinSysteme GmbH Cryo 7 (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 Cryo 7 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.	Similar
Intended Use	The Cryo 7 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	-30°C ± 3°C At an air speed of 210 ± 40 to 600 ± 100 liters/minute.	-30°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	100V - 120V / 50-60Hz	100V – 120V / 50-60Hz	Identical
Main Fuse	16A circuit breaker in main switch	16A circuit breaker in main switch	Identical
Power Consumption	Max. 10A	Max. 9 - 11A	No impact
IP classification	IP20	IPX0	Identical
Design	Internal metal chassis covered by industrial designed plastic housing	Metal enclosure	Similar, not important for the device safety and effectiveness evaluation
Materials	Environmentally approved R452a, closed loop cooling system	Environmentally approved R507, closed loop cooling system	Both environment-ally 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 - 9	1 - 9	Identical

Comparison with the Predicate Device	**SUBJECT DEVICE** **Zimmer MedizinSysteme GmbH** **Cryo 7 (This Submission)**	**PREDICATE DEVICE** **Zimmer MedizinSysteme GmbH** **Cryo V6.0 (K060395)**	**Discussion**
Interface	USB 2.0, RS 232	N/A	Product feature with no effect to safety or effectiveness evaluation
Therapy time, treatment time	1:00 – 100:00 min – 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	R452a Ozone destruction level 0	R507 Ozone destruction level 0	Both environment-ally approved, no impact
Display	10.1 inch touch display	LCD display	Product feature with no effect to safety or effectiveness evaluation
Weight without accessories	60 kg	60 kg	Identical
Dimensions	H 1060 mm x W 500 mm x D 560 mm	H 645 mmm 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: 900-1030 hPa	Temperature: 10 - 35°C Humidity: 20-80% relative humidity without condensation Air pressure: 900-1060 hPa	30hPa lower air pressure has no impact
Storage and Transport	Temperature: -10 - 50°C Humidity: 10-90% relative humidity without condensation Air pressure: 700-1060 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	10°C higher storage temperature and 100 hPa higher air pressure has no influence

Comparison with the Predicate Device	**SUBJECT DEVICE Zimmer MedizinSysteme GmbH Cryo 7 (This Submission)**	**PREDICATE DEVICE Zimmer MedizinSysteme GmbH Cryo V6.0 (K060395)**	**Discussion**
		without condensation Air pressure: 600-1060 hPa	on the device safety and effectiveness evaluation
Environmental Specifications	For indoor use only	For indoor use only	Identical

VII. PERFORMANCE DATA:

The Cryo 7 has been investigated and tested against and complies with the following voluntary standards:

Standards	**Standards Organization**	**Standards Title**
ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text)	ANSI AAMI	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
60601-1-2:2014 (Edition 4.0)	IEC	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
60601-1-6:2013 (Edition 3.1)	IEC	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
62366-1:2015 (Edition 1.0)	IEC	Medical devices – Part 1: Application of usability engineering to medical devices
62304:2015 (Edition 1.1)	IEC	Medical devices software –software life cycle processes
14971:2019-12 (Edition 3.0)	ISO	Medical devices – Application of risk management to medical devices
15223-1:2016 (Edition 3)	ISO	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements
10993-1:2018 (Edition 5)	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 Cryo 7 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 as a result of the changes referenced. The system complies with ES60601-1:2005 + CORR: 1:2006 + CORR. 2:2007 + A1:2012 (Edition 3.1), and IEC 60601-1-2:2014 (Fourth Edition).

VIII. CONCLUSION:

The proposed indications for use for the Cryo 7 are the same as those cleared in K060395. The subject device described in this submission is essentially the same device cleared in K060395. The changes between the two devices have been conducted through the company's Design Controls process. The changes that have been made to the system's hardware, software, mechanical layout and the display, do not affect the intended use, performance or risk profile of the device. Other changes were cosmetic which included new housing for the unit and the new brand name: Cryo 7.

The Cryo 7 is substantially equivalent to the predicate device.