February 6, 2024

Beijing Sano Laser S&T Development Co., Ltd
% Zhao Huifang
Correspondent
Microkn Business Consulting (Shanghai) Co., Ltd.
Room 1319, Block A, No 3699, Gonghexin Road
Jingan District
Shanghai, 200040
China

Re: K233416
Trade/Device Name: Cryojet Plus (SHE-ACP001-1)
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 26, 2023
Received: December 26, 2023

Dear Zhao Huifang:

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,

Tanisha L. Hithe -S
Tanisha L. Hithe -S
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Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical & 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)*
K233416

Device Name
Cryojet Plus (SHE-ACP001-1)

Indications for Use *(Describe)*
Cryojet Plus 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.

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510(k) SUMMARY-K233416

I. Contact Details

Applicant Name: Beijing Sano Laser S&T Development Co., Ltd.

Room 201, 2nd Floor, No.7 Building, Maohuagongchang, NO.1 CAIDA Third Street, Nancai Town, Shunyi District, Beijing, China

TEL: 086-10-57150601

Contact: Hongbo Zhang, CEO

360349720@qq.com

Date Prepared: Oct 06, 2023

II. Device Name

Device Name : Cryojet Plus (Model: SHE-ACP001-1)

Generic Name: Powered Laser Surgical Instrument

Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology (21CFR 878.4810)

Regulatory Class: II

Product Code: GEX

III. Predicate Device

510(k) Number	Product Code	Trade Name	Applicant
K220020	GEX	Cryo 7	Zimmer MedizinSysteme GmbH

This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. Device Description

Cryojet Plus is intended to minimize pain and thermal injury during laser and dermatological treatments and for the temporary topical anesthetic relief for injections. And it shall be used by professionally trained medical operators.

Cryojet Plus is composed of main body (including power supply system, control system, cooling system), power cable, supporting arm rod (a group of supporting rod, two support clips), wind tube, adapters, casters and other accessories. Control system consists of LCD screen display and control board, etc; Cooling system includes compressor, evaporator, radiator, fan, water tank; Power supply system is composed of power cable, filter and ON/OFF switch power.

How It Works: Gaseous refrigerant is compressed into high-temperature and high-pressure gas by high-power compressor and sent to condenser for cooling. Refrigerant can produce cold air by condenser and evaporation system for skin cooling through conduction, evaporation and forced convection. Evaporator absorbs heat in air and vaporizes the heat, then heat is gaseous, then the gas is back to compressor and continue to be compressed. Thus cooling is done through such circulation. Defrosting system melts the frost inside evaporation system into liquid water and discharge the water through drain valve.

Software is used for system initialization, displaying user interface and cooling system control. Parameter setting (therapy time and wind level) can be done by touching LCD screen, thus START/STOP and defrosting of device can be controlled. The software can be used in conjunction with hardware system during treatment to minimize thermal damage to tissues and reduce pain.

V. Intended Use/Indications for use

Cryojet Plus is indicated to be used to: Minimize pain and thermal injury during laser and dermatological treatments and for temporary topical anesthetic relief for injections.

Main components of device are listed below:

Table 2 Main Components of Proposed Device

Components	Function Description
Air Switch	Control of Device Power ON/OFF

Touch Screen	Display User Interface, Operation Control System, Treatment Parameter Setting
Wind Tube	Deliver cold air from blower to adapter.
Adapter	Different sizes of adapters are applicable to different body parts to be treated.

VI. Substantial Equivalence Comparison / Comparison of technological characteristics with the predicate device

The predicate device for this submission is Cryo 7(K220020) from Zimmer MedizinSysteme GmbH that has been approved under K220020.

The submitted proposed device (Cryojet Plus) and predicate device (Cryo 7) are both classified as II. They are both for skin cooling by blowing cold wind to patient's local skin parts (the device is not intended to be in contact with patient). The indications of proposed device (Cryojet Plus) and predicate device (Cryo 7) are the same.

The submitted proposed device (Cryojet Plus) and predicate device (Cryo 7) are based on the same scientific theories:

1. The working theories principles are identical. They both apply compressor cooling. Refrigerant is compressed into high-temperature and high-pressure gas (by high-power compressor) and sent to condenser for cooling and liquefaction. Refrigerant goes through expansion valve for throttle in evaporator and it absorbs heat in air and generate cold air surrounding it. Meanwhile, the fan blows natural air into evaporator for coldness and heat exchange, then the cold air is conducted to skin by wind tube. Forced convection makes skin cooling. Refrigerant absorbs heat in evaporator and becomes evaporated, then back to compressor to continue compression. Thus cooling is done through such circulation.

Defrosting system melts the frost inside evaporation system into liquid water and discharge the water through drain valve.

2. While the wind current flow level range, lowest temperature of output wind, cooling spot coverage area at a distance of 5cm, therapy time and defrost for both devices are identical or similar to reach the indicated effect, they do differ in appearance, size (dimension), weight and the product code of control system. The whole device is supported and moved through casters.

3. Product Components: The two devices are both substantially composed of compressor, evaporator, condenser, DC brushless motor, fan, temperature sensor and wind tubes.

4. Their energy sources are also identical.

The comparison of technical characteristics between proposed device (Cryojet Plus) and predicate device (Cryo 7) are as follows:

1. For Cryojet Plus produced by SANO Laser, there are 3 sizes of adapters (listed below) for therapy on different body parts; for Cryo 7 produced by Zimmer, there is no adapter for choice, wind is blown out from end of wind tube directly. (Vary in cooling spot coverage area at a distance of 5cm).

Item	Adapter Specifications	Size	Intended for use
1	Small Sized Round Adapter		For small area treatment and skin cooling meanwhile (e.g. eyebrow, armpits, forehead.)
2	Medium Sized Square Adapter		For medium area treatment and skin cooling meanwhile (especially used for hair removal on arms, armpits and legs, in conjunction with hair

			removal machine.)
3	Large Sized Square Adapter		For large area treatment and skin cooling meanwhile (especially used for hair removal on thighs, abdomen, in conjunction with hair removal machine.)

2. Different Display Screen Size: Proposed device (Cryojet Plus) screen size is 10.1 inch and predicate device (Cryo 7) screen size is 5 inch;
3. IP Protection Level Difference: Proposed device (Cryojet Plus) is IPX0 and predicate device (Cryo 7) is IP20;
4. Weight Difference: Proposed device (Cryojet Plus) is 65kg and predicate device (Cryo 7) is 60kg.

However, these differences do not affect the substantial equivalence; they are still based on the same technical characteristics to achieve the same purpose. For technical characteristics and operating principle associated with therapy, proposed device (Cryojet Plus) and predicate device (Cryo 7) are identical. Technical similarities and differences between the proposed device and the predicate device are described below in the comparison table. The differences do not raise any new issues of safety or effectiveness.

Table Summary of Similarities and Differences

Specification	PROPOSED DEVICE Beijing Sano Laser S&T Development Co., Ltd. Cryojet Plus (This Submission)	PREDICATE DEVICE Zimmer MedizinSysteme GmbH Cryo 7 (K220020)	Discussion of Similarities/ Differences
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 Cryojet Plus Air Device consists of a compressor, evaporator and fan to cool the patient's skin locally without contact to skin.	The Cryo 7 Cold Air Device consists of a compressor, evaporator and fan to cool the patient's skin locally without contact to skin.	Identical
Intended Use	The Cryojet Plus is intended to minimize pain and thermal injury during laser and dermatological treatments and for temporary topical anesthetic relief for injections.	The Cryo 7 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	-25°C ± 3°C， At an air speed of 200 ± 50 to 620 ± 60 liters/minute.	-30°C ± 3°C， At an air speed of 210 ± 40 to 600 ± 100 liters/minute.	Similar, not significantly different
Cooling Method, Operation Principle	Cooling agent-based condenser and evaporation system. Cold air is produced which is then delivered to skin for skin cooling by conduction, evaporation, and forced convection.	Cooling agent-based condenser and evaporation system. Cold air is produced which is then delivered to skin for skin cooling by conduction, evaporation, and forced convection.	Identical

Specification	PROPOSED DEVICE Beijing Sano Laser S&T Development Co., Ltd. Cryojet Plus (This Submission)	PREDICATE DEVICE Zimmer MedizinSysteme GmbH Cryo 7 (K220020)	Discussion of Similarities/ Differences
Cooling Material	Gas (Air)	Gas (Air)	Identical
Mains Voltage	100V - 120V / 50-60Hz	100V - 120V / 50-60Hz	Identical
Main Fuse	Without circuit breaker in main switch	16A circuit breaker in main switch	No impact
Power Consumption	Max. 8A	Max. 10A	No impact
IP Classification	IPX0	IP20	No impact
Design	Internal metal chassis and framework by industrial designed ABS plastic shell, adapter material is ABS+PC	Internal metal chassis covered by industrial designed plastic shell	Similar, no impact on device safety and effectiveness evaluation
Materials	Environmentally approved R404a, closed loop cooling system	Environmentally approved R452a, closed loop cooling system	No impact

Specification	PROPOSED DEVICE Beijing Sano Laser S&T Development Co., Ltd. Cryojet Plus (This Submission)	PREDICATE DEVICE Zimmer MedizinSysteme GmbH Cryo 7 (K220020)	Discussion of Similarities/ Differences
Cooling Spot Size	Varies in cooling spot size (coverage area) with a distance of 5cm from wind outlet part to skin – 10cm²	Varies in cooling spot size (coverage area) with a distance of 5cm from wind outlet part to skin – 10cm²	The difference of adapter quantity does not raise different questions of safety and effectiveness: SANO Cryojet Plus machine has 3 adapter sizes for choice according to different body parts to be treated; Zimmer machine has only one adapter size.

Specification	PROPOSED DEVICE Beijing Sano Laser S&T Development Co., Ltd. Cryojet Plus (This Submission)	PREDICATE DEVICE Zimmer MedizinSysteme GmbH Cryo 7 (K220020)	Discussion of Similarities/ Differences
Fan Speed Settings	1-10	1-9	Similar, not significantly different
Interface	TTL, PWM	USB 2.0, RS232	Difference in interfaces doesn't affect device safety and effectiveness evaluation
Therapy time, Treatment time	1:00 – 100:00 min – adjustable for users	1:00 – 100:00 min – adjustable for users	Identical
Time Delay to Operate	Immediate from pressing START button when system turns to standby mode	Immediate from pressing START button when system turns to standby mode	Identical
Compatibility with the environment	R404 Ozone destruction level 0	R452a Ozone destruction level 0	Both environmentally approved, no impact

Specification	PROPOSED DEVICE Beijing Sano Laser S&T Development Co., Ltd. Cryojet Plus (This Submission)	PREDICATE DEVICE Zimmer MedizinSysteme GmbH Cryo 7 (K220020)	Discussion of Similarities/ Differences
Display	5.0 inch touch screen display	10.1 inch touch screen display	Different screen sizes have no impact on the device safety and effectiveness evaluation
Net Weight without accessories	65kg	60kg	Similar, not significantly different
Dimensions	H810 mm x W400 mm x D845mm	H1060 mm x W500 mm x D560 mm	Different dimensions have no impact on the device safety and effectiveness evaluation

Specification	PROPOSED DEVICE Beijing Sano Laser S&T Development Co., Ltd. Cryojet Plus (This Submission)	PREDICATE DEVICE Zimmer MedizinSysteme GmbH Cryo 7 (K220020)	Discussion of Similarities/ Differences
Working Environment Temperature and Humidity	Temperature: 10 - 35°C Humidity: 20-80% relative humidity (no condensation) Atmosphere Pressure: 900-1030 hPa	Temperature: 10 - 35°C Humidity: 20-80% relative humidity (no condensation) Atmosphere Pressure: 900-1030 hPa	Identical
Storage and Transport	Temperature: -10 - 50°C Humidity: 10-90% relative humidity (no condensation) Atmosphere Pressure: 700-1060 hPa	Temperature: -10 - 50°C Humidity: 10-90% relative humidity (no condensation) Atmosphere Pressure: 700-1060 hPa	Identical
Environmental Specifications	For indoor use only	For indoor use only	Identical

Performance Data

By investigation and test, Cryojet Plus has been considered to comply with the following voluntary standards:

Standards	Standards Organization	Standards Title
IEC 60601-1:2005;A1:2012;A2:2020	IEC	Medical electrical equipment-Part1:General requirements for basic safety and essential performance
IEC 60601-1-2:2014	IEC	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
IEC 60601-1-6:2013	IEC	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 62366-1:2015	IEC	Medical devices – Part 1: Application of usability engineering to medical devices
IEC 62304:2015	IEC	Medical devices software –software life cycle processes
ISO 14971:2019-12	ISO	Medical devices – Application of risk management to medical devices
ISO 15223-1:2016	ISO	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements
ISO 13485:2016	ISO	Medical devices – Quality management systems--

		Requirements for regulatory purposes
ISO 10993-1:2018	ISO	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

Software Verification and Validation Testing

After evaluation on specified use conditions, it could be proved that the technical design (including software flow and device application) of Cryojet Plus is suitable to fulfill the specified intended use. In both formative and summative testing performed, no application problems were found that could lead to any risk for the user, patient or the third parties.

The verification of software requirements was performed according to 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 as per ISO 10993-1. Since the device is not intended to be in contact with the patient, and the user wears medical gloves when touching the device, there is no additional biocompatibility requirement for 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 IEC 60601-1:2005 + A1:2012+ A2:2020, and IEC 60601-1-2:2014+ A1:2020 .

Non-clinical Testing

Non-clinical testing for Cryojet Plus included electrical safety testing according to IEC 60601-1, electromagnetic compatibility testing according to IEC 60601-1-2. The device has been assessed for the requirement of biocompatibility testing as per ISO 10993-1. Since the device is not intended to be in contact with the patient, and the user wears medical gloves when touching the device, there is no additional biocompatibility requirement for device. In addition, software verification and validation was completed.

Clinical Testing

No clinical testing is included in this 510(k).

Summary / Conclusion

The Cryojet Plus are substantially equivalent to the Cryo 7 in intended use, device characteristics and application parameters.