July 16, 2026

Beijing Nubway S&T Co., Ltd.
% Lena Zhang
RA Manager
Tianjin Xinnuocheng Medical Technology Co., LTD.
Rm. 1505, Wanhai Bldg., Dazhigu Sub-District
Hedong District
Tianjin, 300170
China

Re: K261674
Trade/Device Name: Skin Air Cooling System (QALF-01)
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: May 20, 2026
Received: May 21, 2026

Dear Lena Zhang:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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: 2026.07.16 16:00:18 -04'00'

Tanisha Hithe
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261674

Please provide the device trade name(s).

Skin Air Cooling System (QALF-01)

Please provide your Indications for Use below.

Skin Air Cooling System is indicated to be used to: Minimize pain and thermal injury during laser and dermatological treatments and for temporary topical anesthetic relief for injections.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

1. Date of Preparation: 2026/06/28

2. Sponsor Identification

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3. Designated Submission Correspondent

Ms. Lena Zhang

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4. Identification of Proposed Device

Trade Name: Skin Air Cooling System (QALF-01)
Common Name: Powered Laser Surgical Instrument

Regulatory Information
Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification: II
Product Code: GEX
Regulation Number: 878.4810
Review Panel: General & Plastic Surgery

5. Identification of Predicate Device(s)

Predicate device 1:
510(k) Number: K233416
Product Name: Cryojet Plus (SHE-ACP001-1)
Manufacturer: Beijing Sano Laser S&T Development Co., Ltd.

Predicate Device 2:
510(k) Number: K220020
Product Name: Cryo 7
Manufacturer: Zimmer MedizinSysteme GmbH

6. Device Description

The Skin Air Cooling System is composed of main unit (including power supply system, control system, cooling system), 4 different sizes of air outlet,air duct, air duct support rod, power cord, storage platform, casters and other accessories. The power supply system is composed of power cable, air switch, key switch and emergency stop switch power; the control system consists of LCD screen display and control panel, etc; the cooling system includes compressor, evaporator, radiator, fan, water tank, etc.

How it works: Gaseous refrigerant is compressed into high-temperature and high-pressure gas by high-power compressor and sent to condenser for cooling and liquefaction. 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 (temperature and air volume level) can be done by touching LCD screen, and the Stand by/ready 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.

7. Indication For Use Statement:

Skin Air Cooling System is indicated to be used to: Minimize pain and thermal injury during laser and dermatological treatments and for temporary topical anesthetic relief for injections.

8. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

Item	Proposed Device	Predicate Device 1 K233416	Predicate Device 2 K220020	Remark
Device name	Skin Air Cooling System	Cryojet Plus (SHE-ACP001-1)	Cryo 7	/
Classification Regulation	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	SAME
Classification	II	II	II	SAME
Product Code	GEX	GEX	GEX	SAME
Regulation Name	Laser surgical instrument for use in general and plastic surgery and in dermatology	Laser surgical instrument for use in general and plastic surgery and in dermatology	Laser surgical instrument for use in general and plastic surgery and in dermatology	SAME
Indications for use	Skin Air Cooling System is indicated to be used to: Minimize pain and thermal injury during laser and dermatological treatments and for temporary topical anesthetic relief for injections.	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.	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.	SAME
Device Description	The Skin Air Cooling System consists of a compressor, evaporator and fan to cool the patient's skin locally without contact to skin.	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.	SAME
Air outlets	1. Small Sized Round Air outlet: φ 10mm  For small area treatment and skin cooling meanwhile (e.g. eyebrow, armpits, forehead.) 2. Medium Sized Square Air outlet: 12 * 4mm	1. Small Sized Round Adapter:  For small area treatment and skin cooling meanwhile (e.g. eyebrow, armpits, forehead.) 2. Medium Sized Square Adapter:	there is no adapter for choice, wind is blown out from end of wind tube directly.	Analysis(1)

	 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 Air outlet: 27 * 5mm, 43* 5mm   For large area treatment and skin cooling meanwhile (especially used for hair removal on thighs, abdomen, in conjunction with hair removal machine.)	 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.)		
Performance Characteristics	-30℃ ± 3°C, At an air speed of 200±50 to 620 ±	-25℃ ± 3°C, At an air speed of 200 ± 50 to 620 ±	-30°C ± 3°C, At an air speed of 210 ± 40 to	The temperature is

Measurement at device outlet	60 liters/minute.	60 liters/minute.	600 ± 100 liters/minute.	SAME with Predicate Device 2，the air speed is SAME with Predicate Device 1
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.	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.	SAME
Cooling Material	Gas (Air)	Gas (Air)	Gas (Air)	SAME
Mains Voltage	AC110V～120V, 50/60Hz	100V - 120V / 50-60Hz	100V - 120V / 50-60Hz	SAME
Main Fuse	Without circuit breaker in main switch	Without circuit breaker in main switch	16A circuit breaker in main switch	SAME with Predicate Device 1
Power Consumption	Max. 12A	Max. 8A	Max. 10A	Analysis(2)
IP Classification	IPX0	IPX0	IP20	SAME with Predicate Device 1
Design	Internal metal chassis and framework by industrial designed ABS plastic shell, adapter material is ABS+PC.	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.	SAME with Predicate Device 1
Materials	Environmentally approved R404a, closed loop cooling system.	Environmentally approved R404a, closed loop cooling system.	Environmentally approved R452a, closed loop cooling system.	SAME with Predicate Device 1
Cooling Spot Size	Varies in cooling spot size (coverage area) with a distance of 5cm from wind outlet part to skin - $10cm^2$.	Varies in cooling spot size (coverage area) with a distance of 5cm from wind outlet part to skin – $10cm^2$	Varies in cooling spot size (coverage area) with a distance of 5cm from wind outlet part to skin – $10cm^2$	SAME
Fan Speed Settings	1-6	1-10	1-9	Analysis(3)

Interface	RS232、TTL	TTL, PWM	USB 2.0, RS232	Analysis(4)
Therapy time, Treatment time	adjustable for users	1:00 – 100:00 min – adjustable for users	1:00 – 100:00 min – adjustable for users	Analysis(5)
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	Immediate from pressing START button when system turns to standby mode	SAME
Compatibility with the environment	R404 Ozone destruction level 0	R404 Ozone destruction level 0	R452a Ozone destruction level 0	SAME with Predicate Device 1
Display	8.0 inch touch screen display	5.0 inch touch screen display	10.1 inch touch screen display	Analysis(6)
Net Weight without accessories	87kg	65kg	60kg	Analysis(6)
Dimensions	H955 mm x W400 mm x D840mm	H810 mm x W400 mm x D845mm	H1060 mm x W500 mm x D560 mm	Analysis(6)

Analysis:

Analysis(1)

The air outlets is similar with predicate device 1, the proposed device has 4 sizes of air outlet, while predicate device 1 has 3 sizes of air outlet, but as it has similar specifications and the same intended use, the difference has no impact on device safety and effectiveness.

Analysis(2)

The proposed device has similar power consumption with the predicate devices, with no significant difference, the difference will not affect the safety and effectiveness of the proposed device.

Analysis(3)

There is difference on the fan speed setting, but the proposed device has the same air speed range (200±50 to 620±60 liters/minute) with the predicate device 1, the speed setting difference will not affect the safety and effectiveness of the proposed device.

Analysis(4)

There is difference on the interface, the proposed device complies with electrical safety standard IEC 60601-1, the interface difference will not affect the device safety and effectiveness.

Analysis(5)

The proposed device and the predicate devices all can adjust the treatment time as needed, the proposed device has no time limit, and the difference in range limit of the time adjustment doesn't affect device safety and effectiveness.

Analysis(6)
There are differences on the screen sizes, net weight and dimensions, and the different screen sizes, net weight and dimensions have no impact on the device safety and effectiveness.

9. Non-Clinical Testing

Non clinical tests were conducted to verify that the proposed device met all design specifications and to support the Substantial Equivalence determination.

Electrical safety and electromagnetic compatibility (EMC)
Testing was conducted to demonstrate that the proposed device complies with the following standards:

- AAMI/ANSI ES60601-1:2005(R) 2012&A1:2012 and A2:2021, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014+A1:2020, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

Software Verification and Validation Testing
Software verification and validation testing were conducted 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 documentation level for this device was determined to be "basic."

Specification Testing
Testing was conducted to validate that the proposed device meets design specifications for temperature range and air speed using each air outlet at each speed setting.

10. Clinical Testing

No clinical study is included in this submission.

11. Conclusion

The data obtained from the nonclinical tests support that the device is as safe, as effective, and performs as well as the legally marketed predicate devices.