February 14, 2024

Daeshin Enterprise Co., Ltd.
% Seung Ahn
CEO
Chemron FDA Korea
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Gangnam-gu, Seoul 06099
Korea, South

Re: K231514
Trade/Device Name: Azure
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: January 12, 2024
Received: January 12, 2024

Dear Seung Ahn:

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,

Shlomit Halachmi -S

Digitally signed by Shlomit Halachmi -S
Date: 2024.02.14 15:38:39 -05'00'

Shlomit Halachmi

for

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

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)*
K231514

Device Name
Azure

Indications for Use *(Describe)*
Azure(DS-22CO) is intended for use in non-fractionated mode for Incision, Excision, Ablation, Vaporization, and Coagulation of Human body soft Tissues in Dermatology, Plastic surgery, General Surgery, Gynecology, Neurosurgery, and in Podiatry.

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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510(k) Summary

510(k) number: K231514

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

Date Prepared: Feb 13, 2024

I. Submitter

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II. Subject Device

- Trade (Proprietary) Name: Azure
- Manufacturer: DAESHIN ENTERPRISE CO., Ltd.
- Common Name: Powered Laser Surgical Instrument
- Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
- Product Code: GEX
- Review Panel: General & Plastic Surgery
- Regulation Number: 21 CFR 878.4810
- Device Classification: Class II
- Submission Type: 510(k) Traditional

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III. Predicate Device

The subject device is substantially equivalent to the following predicate device, which is legally marketed.

Predicate Device	**510(k) Number**	**Company Name**
Finexel	K213557	SNJ Co., Ltd

IV. General Description

Azure consists of main body, articulated arm, handpiece, foot switch, power cord, protective glasses. In a main body, there are a monitor displaying all information needed by an operator at a glance and a touch LCD manipulated by simple hand touch, which facilitates operation of the equipment at user's convenience. The laser output is released by the foot switch. This laser operation device uses CO_2 medium based wave of 10.6μm.

V. Indications for Use

Azure(DS-22CO) is intended for use in non-fractionated mode for Incision, Excision, Ablation, Vaporization, and Coagulation of Human body soft Tissues in Dermatology, Plastic surgery, General Surgery, Gynecology, Neurosurgery, and in Podiatry.

VI. Comparison of Technological Characteristics with the Predicate Device

Azure has a substantially equivalent to the predicated device with respect to the intended use and basic technological characteristics. Please refer to the next page for the comparison table.

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Category	Predicate Device (SNJ Co., Ltd)	Subject Device (DAESHIN ENTERPRISE CO., Ltd.)	Decision	Explanation
Product Name	Finexel	Azure	-	-
Manufacturer	SNJ Co., Ltd	DAESHIN ENTERPRISE CO., Ltd.	-	-
510K Number	K213557	K231514	-	-
Classification Product Code	GEX	GEX	Same	-
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	Same	-
Class	Class II	Class II	Same	-
Intended Use	Finexel CO2 laser system is intended for use isn non-fractionated mode for Incision, Excision, Ablation, Vaporization, and Coagulation of Human body soft Tissues in Dermatology, Plastic surgery, General Surgery, Gynecology, Neurosurgery, and in Podiatry.	Azure(DS-22CO) is intended for use in non-fractionated mode for Incision, Excision, Ablation, Vaporization, and Coagulation of Human body soft Tissues in Dermatology, Plastic surgery, General Surgery, Gynecology, Neurosurgery, and in Podiatry.	Same	-
Dimension and Weight of Device	350(W) x 400(L) x 1000(H) mm Approx. 50kg	330(W) x 330(L) x 1060(H) mm Approx. 45kg	Different	The dimensions and weight of the subject device are different from those of the predicate device. However, the dimension and weight difference is only in physical specification, which will not raise any issues in safety and effectiveness.
Wavelength	10,600nm	10,600nm	Same	-

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Laser Type (Source)	CO2 Laser	CO2 Laser	Same	-
Pulse Frequency	N/A	1Hz ~ 500Hz	Different	The pulse frequency of the subject device is different from that of the predicate device, but it falls within the range of values for the predicate device. Therefore, it will not raise any issues in safety and effectiveness.
Pulse Duration	N/A	60 μs ~ 900μs	Different	The pulse duration of the subject device is different from that of the predicate device, but it falls within the range of values for the predicate device. It will not raise any issues in safety and effectiveness.
Energy (max)	N/A	30W (CW mode) 15J (Ultra mode)	Different	It is different from the Predicate Device, but it is included within the range of the value the Predicate Device and it will not raise any issues in safety and effectiveness.
Spot Size	N/A	0.4mm(100mm Handpiece) 0.2mm(50mm Handpiece) 0.2~1.0mm(Zoom Handpiece)	Slightly Different	The difference in spot size is very small, approximately 0.2mm, so it will not affect safety or effectiveness.
Fluency (Energy Density)	N/A	72243J/cm^2 (cw, 50mm)	Different	Fluency of the subject device is different from that of the predicate device, but it falls within the range of values for the predicate device. It will not raise any issues in safety and effectiveness.
Aiming laser	5mW, 650nm, InGaAIP	5mW, 650nm, InGaAIP	Same	-
Laser Delivery	Articulated Arm	Articulated Arm	Same	-
User Interface	LCD Touch Screen	LCD Touch Screen	Same	-
Standards met	IEC 60601-1-1 IEC 60601-1-2 IEC 60601-1-6 IEC 60601-2-22 IEC 60825-1	IEC 60601-1-1 IEC 60601-1-2 IEC 60601-1-6 IEC 60601-2-22 IEC 60825-1	Same	-

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VII. Testing Data

i. Non-Clinical Testing

Non-Clinical Testing was performed for this 510(k) Notification. The following performance data were provided in support of the substantial equivalence determination:

- Biocompatibility Testing – The biocompatibility evaluation for the subject device was conducted in accordance with the guidance "Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" as recognized by FDA.
- Shelf Life Testing – Expected service life rationale report has been attached in this submission.
- Software – Verification and validation testing was conducted on the software interface and firmware and the documentation provided is as recommended in the FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."
- Electromagnetic Compatibility and Electrical Safety – Electromagnetic Compatibility and Electrical Safety testings were conducted on Azure. The following standards were complied with the device:

  - Electromagnetic Compatibility: *IEC 60601-1-2*

  - Electrical Safety Testing: *IEC 60601-1*

  - Laser Safety: *IEC 60825-1*

  - Usability: *IEC 60601-1-6*

- Performance Testing – Performance testing was conducted on Azure according to the following standard:

  - *IEC 60601-2-22*

The subject device passed all tests and successfully met all acceptance criteria and test requirements.

ii. Clinical Testing

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate devices. These types of devices, including the predicated devices, have been on the market for many years with a proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

VIII. Conclusion

Based on the similarities of the subject and predicate device, it is concluded that Azure is substantially equivalent to the predicate device. The summary submitted includes only information that is also covered in the body of the 510(k). It does not include any puffery or unsubstantiated labeling claims, any raw data, any trade secret or confidential commercial information and any patient identification information.