January 16, 2024

Dalim Medical Corp.
Dave Kim
Official Correspondent
102-606 and 609(Ho), 397, Seokcheon-ro
Bucheon-si, Gyeonggi-do 14449, Korea, South

Re: K232062
Trade/Device Name: Uni-port
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: OTJ
Dated: July 7, 2023
Received: July 11, 2023

Dear Dave Kim:

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2024.01.16 12:56:07 -05'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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and Infection Control Devices
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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.

Submission Number *(if known)*

K232062

Device Name

Uni-port

Indications for Use *(Describe)*

The Uni-port is intended to provide access for multiple instruments and/or endoscope to the abdominal cavity through a single incision during minimally invasive laparoscopic surgery.

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
K232062

The following 510(k) summary is being submitted as required by 21 CFR Part 807.92;

5.1 Submitter:

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Date Prepared: December 11, 2023

5.2 Device Identification

Device Trade Name	Uni-port
Model	UP01F, UP03F, UP04F, UP01FL, UP03FL, UP04FL, UP04FSP, UP04FSP-A, UP04FSP-B, UP04FSP-C, UP01FV2-D, UP01FLV2-D, UP03FV2-B, UP03FV2-F, UP03FLV2-B, UP03FLV2-F, UP04FV2-B, UP04FV2-F, UP04FLV2-B, UP04FLV2-F, UP03FSV2SP, UP03FSV2SP-A, UP03FV2SP, UP03FV2SP-A, UP03FV2SP-B, UP04FV2SP, UP04FV2SP-A, UP04FV2SP-B
Common Name	Single Use Manual Operated Surgical Retractor
Classification Name, Number	Laparoscope, general & plastic surgery (21 CFR 876.1500)
Device Classification	II
Product Code	OTJ

5.3 Predicated or legally marketed devices which are substantially equivalent

Predicated device: K141715, "GLOVE PORT", manufactured by "NELIS Corp."
Reference device: K112196, "OCTO™ port", manufactured by Dalim SurgNET Co.

5.4 Device Description

Uni-port is a single use manual operated surgical retractor comprised of three components; main body, wound retractor and filter

The main body consist of combinations of several ports of various size (5mm, 12mm, 15mm and 28mm).

The wound retractor is a flexible polyurethane film that has two rings attached at each end and a T-handle connected with thread for easily removal after procedure. The single (lower) ring is inserted into the abdomen for fixation and double (upper) ring is connected with main body.

The filter is provided separately to filter out harmful gas generated in the abdominal cavity, it is easy to ensure a clear view.

5.5 Statement of Indication for use

The Uni-port is intended to provide access for multiple instruments and/or endoscope to the abdominal cavity through a single incision during minimally invasive laparoscopic surgery.

5.6 Non-clinical Test Conclusion

The following properties were tested based on the referenced standards. All the test results support substantial equivalence to the predicate devices.

- Shelf- Life Test
- ISO 10993-5- Cytotoxicity
- ISO 10993-10 - Sensitization & Intracutatneous Reactivity
- ISO 10993-11 – Acute systemic toxicity & Pyrogens
- Other bench testing- Surface, Measurement, Tensile strength, Airtightness, Fatigue resistance, Extractable substances, Comparative performance

Bench test results allowed to conclude that Uni-port is substantially equivalent to the predicate devices for its intended use.

5.7 Technical Characteristics and Substantial Equivalence

The Uni-port is substantially equivalent to GLOVE PORT (K141715). The following comparison table is presented to demonstrate substantial equivalence.
The Uni-port does not have a new intended use. It shows equivalent specifications with the predicate devices in most of the parameters. However, there are no significant differences in some parameters [Port No., Ring diameter] between the Uni-port and Predicate Device [GLOVE PORT (K141715)].

Table 1. General Device Characteristics Comparison Table

Item	Subject	Predicate device	Remark
Manufacturer	**Dalim Medical Corp.**	NELIS Corp.	**-**
Product Name	Single Use Manual Operated Surgical Retractor	Endoscopy Surgery Instrument	-
Brand Name	Uni-port	GLOVE PORT	-
510K No	K232062	K141715	-
Design			-
Indications for Use	The Uni-port is intended to provide access for multiple instruments and/or endoscope to the abdominal cavity through a single incision during minimally invasive laparoscopic surgery.	The Glove Port Is intended to provide access for multiple instruments and/or endoscope to the abdominal cavity through a single incision during minimally invasive laparoscopic surgery.	Same as predicate
Prescription/over-the-counter use	Prescription	Prescription	Same as predicate
Port No.	1ea, 3ea, 4ea	3ea, 4ea	The difference in the number of ports is only the difference in the number of instruments used in surgery. It does not

			affect the safety and effectiveness of the device.
Absolute size	10mm~25mm	10mm~25mm	Same
Material	Polyurethane	Polyurethane	Same
Disposable	Yes	Yes	Same
Ring Diameter	63 / 93 mm	60 ~ 95mm	Similar
Installation and abdominal wall inner fixation	Wound retractor ring being fixed inside the abdominal wall inside.	Wound retractor ring being fixed inside the abdominal wall inside.	Same as predicate
Sterilization method	EO gas sterilization	EO gas sterilization	Same as predicate
Certification	CE 2165	CE0120, ISO 9001:2008, ISO 13485:2003, Registration of KFDA	No significant dfference

Table 2. General Device Characteristics Comparison Table

Item	Subject	Reference device	Remark
Manufacturer	**Dalim Medical Corp.**	Dalim SurgNET Co.	-
Product Name	Single Use Manual Operated Surgical Retractor	Laparoscopic Accessory	-
Brand Name	Uni-port	OCTO™ port	-
510K NO	K232062	K112196	-
Design			-
Indications for Use	The Uni-port is intended to provide access for multiple instruments and/or endoscope to the abdominal cavity through a single incision during minimally invasive laparoscopic surgery.	The OCTO™Port is intended to use as a multiple instrument and/or camera port during minimally invasive abdominal laparoscopic surgery.	Same
Prescription/over-the-counter use	Prescription	Prescription	Same
Port No.	1ea, 3ea, 4ea	1ea, 3ea, 4ea	Same
Absolute size	10mm~25mm	15~50mm	Similar
Material	Polyurethane	Silicone	Different
Disposable	Yes	Yes	Same
Installation and	Wound retractor ring being	Wound retractor ring	Same as predicate

abdominal wall inner fixation	fixed inside the abdominal wall inside.	being fixed inside the abdominal wall inside.	
Sterilization method	EO gas sterilization	EO gas sterilization	Same as predicate
Certification	CE 2165	CE 0120	No significant dfference

Although the subject device and predicate device are no significant differences in some parameters, the differences do not affect the substantial equivalence of the subject device when compared to the predicate device.

5.8 Conclusion

Based on the testing results, Dalim Medical Corp. concludes that the subject device is substantially equivalent to the predicate device.

5.9 Declarations

This summary includes only information that is also covered in the body of the 510(k).
This summary does not contain any puffery or unsubstantiated labeling claims.