November 22, 2024

Advamedix, GmbH
% Marianne Jacklyn
President and Principal Consultant
TRAXN Consulting LLC
1235 Swift Shore Circle
West Linn, Oregon 97068

Re: K242927
Trade/Device Name: Suction Irrigation Tubing Set
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: September 24, 2024
Received: September 24, 2024

Dear Marianne Jacklyn:

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.

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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2024.11.22 13:02:14 -05'00'

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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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)*
K242927

Device Name
Suction Irrigation Tubing Set

Indications for Use *(Describe)*
The Disposable Suction Irrigation Tubing Set is indicated for use in patients undergoing a laparoscopic surgical procedure. It is designed to deliver sterile irrigation normal saline to surgical sites during laparoscopic procedures and to evacuate blood, tissue debris, and smoke from the surgical site to aid visualization.

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.

510(k) Summary

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

1 Contact Details: 21 CFR 807.92(a)(1)

Applicant Name	Advamedix, GmbH
Applicant Address	Greschbachstr 3/3, OG Karlsruhe 76229 Germany
Applicant Contact Telephone	Phone: +49 721 94552
Applicant Contact	Dr. Islam Abed, Director
Applicant Contact Email	abed@advamedix.net
Correspondent Name	TRAXN Consulting LLC
Correspondent Address	1235 Swift Shore Circle, West Linn, Oregon 97068 United States
Correspondent Contact Telephone	(503) 729-9633
Correspondent Contact	Ms. Marianne D. Jacklyn
Correspondent Contact Email	mjacklyn@traxnconsulting.com

2 Device Name: 21 CFR 807.92(a)(2)

Trade Name	Suction Irrigation Tubing Set
Common Name	Tubing
Classification Name	Endoscope and Accessories
Regulation Number	876.1500
Product Code(s)	GCJ

3 Legally Marketed Predicate Devices: 21 CFR 807.92(a)(3)

K141592, Unimicro Suction Irrigation Tubing Set

4 Device Description Summary: 21 CFR 807.92(a)(4)

The Disposable Suction Irrigation Tubing Set consists of a grip body equipped with two trumpet style valves, a probe, and connecting lines of tubing; one set designed to attach a supply of irrigation normal saline, and the other designed to attach to suction equipment (aspiration pump). The valves allow for control of irrigation and aspiration during a surgical procedure. The handpiece of the suction irrigator is designed to allow instruments to be introduced through the suction irrigation probe to reach the

operative site. The instrument adapter is adjustable to allow a variety of instruments and diameters. The device is packaged as sterile with a shelf life of 3 years and is for single use only.

5 Intended Use/Indications for Use: 21 CFR 807.92(a)(5)

The Disposable Suction Irrigation Tubing Set is indicated for use in patients undergoing a laparoscopic surgical procedure. It is designed to deliver sterile irrigation normal saline to surgical sites during laparoscopic procedures and to evacuate blood, tissue debris, and smoke from the surgical site to aid visualization.

6 Technological Comparison: 21 CFR 807.92(a)(6)

Device & Predicate Device(s)	**K242927**	**K141592**
Indications for Use	The Disposable Suction Irrigation Tubing Set is indicated for use in patients undergoing a laparoscopic surgical procedure. It is designed to deliver sterile irrigation normal saline to surgical sites during laparoscopic procedures and to evacuate blood, tissue debris, and smoke from the surgical site to aid visualization.	The Unimicro Suction Irrigation Tubing set is available with an array of probe designs to facilitate lavage during laparoscopic surgery. This device has applications in laparoscopic gynecologic, general, thoracic and urology procedures to provide suction and irrigation functions to help flush blood and tissue debris from the operative site during laparoscopy to aid visualization.
Principles of Operation	The Disposable Suction Irrigation Tubing is a sterile, single-use and multifunctional instrument which achieves two functions in one device. This device is available both in a 5mm and 10mm instrumentation with double spike tubing. The device depends on a laparoscopic operation pump to supply power, including irrigation and suction. There are two series: one that can aspirate the smoke out of the abdomen produced in laparoscopic surgical procedures with the negative pressure suction equipment, and other that cannot evacuate the smoke.	The suction irrigation set consists of a hand piece equipped with two trumpet style valves, a probe, and connecting lines of tubing, one set designed to attach to a supply of irrigation fluid, and the other designed to attach to an aspiration pump. The valves allow controlled irrigation and aspiration during a surgical procedure. The hand piece of the suction irrigator is designed to allow instruments to be introduced through the suction irrigation probe to reach the operative site. The instrument adapter is adjustable to allow a variety of instruments and diameters.
Main Components	Probe, handpiece, connecting lines of tubing	Probe, handpiece, connecting lines of tubing
Models	Suction Irrigation Set	Suction Irrigation Set

Device & Predicate Device(s)	**K242927**	**K141592**
	Suction Irrigation Set With Smoke Evacuation	Suction Irrigation Set With Smoke Evacuation
Dimensions (Overall)	Outer Diameter: 5.2 mm – 10.2 mm	Outer Diameter: 5.2 mm – 10.2 mm
	Inner Diameter: 4.6 mm – 9.2 mm	Inner Diameter: 4.6 mm – 9.2 mm
	Length: 280 mm - 450 mm	Length: 280 mm - 450 mm

7 Non-clinical Tests Summary 21 CFR 807.92(b)

A series of nonclinical bench tests were performed to assess the safety and effectiveness of the Advamedix Suction Irrigation Tubing Sets. All tests were conducted utilizing devices post sterilization, and post accelerated aging. The performance testing conducted on the subject device and predicate device are listed below:

- Air tightness test
- Smooth test
- Tensile strength test
- Tubing collapse test
- Irrigation fluid / aspiration fluid flow test

8 Conclusion from nonclinical tests (21 CFR 807.92(b)(3))

The conclusions drawn from the technological comparison and nonclinical testing demonstrate that the proposed subject devices raise no new questions of safety or effectiveness, and substantially equivalent in terms of safety and effectiveness as the legally marketed predicate devices for the proposed indications for use.