October 4, 2024

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

Re: K241052
Trade/Device Name: Bladeless Trocar; Bladed Trocar; Hasson Trocar
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: September 5, 2024
Received: September 6, 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: 2024.10.04 17:26:30 -04'00'

Long Chen, Ph.D.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241052

Device Name

Bladeless Trocar;
Bladed Trocar;
Hasson Trocar

Indications for Use *(Describe)*

The Bladeless Trocar, Bladed Trocar, and Hasson Trocar have application in a variety of laparoscopic procedures to provide a port of entry for laparoscopic instruments.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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
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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	Bladeless Trocar, Bladed Trocar, Hasson Trocar
Common Name	Trocar
Classification Name	Endoscope and Accessories
Regulation Number	876.1500
Product Code(s)	GCJ

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

K141594, Unimicro Trocar Kit, models: Auto-Locking Trocar, Hasson Trocar, Bladeless Trocar

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

The Disposable Surgical Trocar is composed of two parts, one obturator and one guide tube (cannula). The obturator of the Bladeless Trocar is plastic allowing the surgeon to dilate between tissues. The obturator of Bladed Trocar is made of PC and a small blade made of stainless steel, which is released when the surgeon presses the trocar to help with cutting.

The Disposable Surgical Trocar Kit, bladed or bladeless, has one obturator and two cannulas or two obturators and four cannulas.

The device is for single use only. This device is sterilized with ethylene oxide and has a shelf life of 3 years.

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

The Bladeless Trocar, Bladed Trocar, and Hasson Trocar have application in a variety of laparoscopic procedures to provide a port of entry for laparoscopic instruments.

6 Indications for Use Comparison: 21 CFR 807.92(a)(5)

The indications for use are the same for the proposed devices and the predicate devices.

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

Device & Predicate Device(s)	**K241052**	**K141594**
Principles of Operation	During the operation, the trocar sleeve and the obturator are used together. The surgeon uses the obturator to expand the incision of the abdomen and penetrates the trocar sleeve through the abdominal surface of the human body into the abdominal cavity, thereby delivering gas to the abdominal cavity and establishing a path of entry for surgical instruments.	During the operation, the trocar sleeve and the obturator are used together. The surgeon uses the obturator to expand the incision of the abdomen and penetrates the trocar sleeve through the abdominal surface of the human body into the abdominal cavity, thereby delivering gas to the abdominal cavity and establishing a path of entry for surgical instruments.
Main Components	obturator, cannula	obturator, cannula
Models	Bladeless Bladed Hasson	Bladeless Bladed Hasson
Dimensions (Overall)	Diameter: 5-12 mm Length: 100 mm	Diameter: 5-12 mm Length: 70 – 120 mm

8 Non-clinical and/or Clinical Tests Summary & Conclusions: 21 CFR 807.92(b)

The subject device trocar models (Bladeless Trocar, Bladed Trocar, Hasson Trocar) are manufactured by the same company that manufactures those of the predicate device (Unimicro) and are identical to those cleared under K141594. As such, performance testing is not required.