July 22, 2026

Gimmi GmbH
Nicolas Geisheimer
Regulatory Affairs Representative
Carl-Zeiss-Str. 6 -
Tuttlingen, BW 78532
Germany

Re: K261179
Trade/Device Name: AlphaTriPart - Monopolar MIC Instruments
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 25, 2026
Received: June 25, 2026

Dear Nicolas Geisheimer:

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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.07.22 15:27:04 -04'00'

Colin K. Chen, Ph.D.
Acting 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.	K261179

Please provide the device trade name(s).

AlphaTriPart - Monopolar MIC Instruments

Please provide your Indications for Use below.

Instruments for laparoscopic surgery are intended for cutting, resecting, gripping and coagulation of body tissue.

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)

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510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92. All data included in this document are accurate and complete to the best of Gimmi´s knowledge.

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Regulatory Affairs

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Date of Preparation: July 22nd, 2026

Device Identification:

Trade name:
AlphaTriPart – Monopolar MIC Instruments

Common name:
Monopolar MIC Instruments

Classification name:
Electrosurgical, cutting & coagulation & accessories

Product Code: GEI

Regulation: 21 CFR 878.4400

510(k) Type: Traditional

Predicate Device: CLICKLINE; K954122, K935071; KARL STORZ SE & Co. KG
Laparoscopic Instruments, 3parts; K060232; Trokamed GmbH

Device Description:

The Gimmi AlphaTriPart system is a monopolar laparoscopic system consisting of 3-parts. One part is the handle, second the sheath and the third part is the instrument insert which is inserted through the sheath into the handle. Handle and sheath are isolated. Therefore, the electrical monopolar current (only when pressing the foot pedal of the HF unit) is flowing from the plug, where the HF cable is fixed, to the distal end of the instrument tip.

The Luer Lock cleaning port allows flushing of the inside of the sheath during reprocessing. Sheath and insert are rotatable. For the handle there are different types available – with or without ratchet. For AlphaTriPart there is in addition a variant with non-locking handle available.

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Principle of operation / mode of action:
The monopolar products are monopolar forceps and scissors electrodes, which consist of two movable jaw parts. The movement is carried out by a pull/ push wire, which is connected to the corresponding mouth part via a joint. Shaft and handles are isolated. The instrument jaw parts are available in different shapes and figures. The dimensions of the mouth parts as well as of the electrodes were designed for use through a trocar.

Indication:
Instruments for laparoscopic surgery are intended for cutting, resecting, gripping and coagulating of body tissue.

Patient population

Patients	Human medicine
Age	Use on Adults only
Health condition	Relevant, because patient is treated under anesthesia.

Note: The products must be used only in medical facilities by trained and skilled medical personnel. The products must not be used if, according to a qualified physician, the general condition of the patient is not adequate or if the endoscopic methods are contraindicated.

Technological Characteristics:
The products under consideration & the predicate device(s) are similar in all application related points and technical characteristics, including being monopolar and connecting to an HF generator. The labeling is consistent with the valid requirements. Both are made of the same materials, have identical indications and contraindications, and are used at the same site in the body. Some minor differences exist, such as the color of the PEEK handle and the connection type between parts. However, these variations do not impact safety or effectiveness. Biocompatibility, mechanical, and electrical tests were successfully completed for all products. Consequently, the product under consideration and the predicate devices are considered to be substantially equivalent.

Non- Clinical Performance Data:
The AlphaTriPart Instruments are tested according to the following standards:

- IEC 60601-2-2
- IEC 60601-1-6
- IEC 62366-1
- ISO 10993-1
- ISO 10993-5
- ISO 10993-10
- ISO 10993-11

Additional bench testing for performance verification and validation purposes:

- Impact test
- Drop test
- Reduction of molding stresses

Biological characteristics:
The predicate and the subject devices uses the same materials in contact with the same human tissues or body fluids for a similar kind and duration of contact and similar release characteristics of substances, including degradation products and leachables.

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Clinical characteristics:

The predicate and the subject devices are used for the same clinical condition or purpose, including similar severity and stage of disease, at the same site in the body, in a similar population, including as regards age, anatomy and physiology; has the same kind of user; has similar relevant critical performance in view of the expected clinical effect for a specific intended purpose.

Clinical Performance Data:

No Clinical data is required for this submission

Conclusion:

The AlphaTriPart Instruments and the predicate device are similar in all application related points and technical characteristics, including being monopolar and connecting to an HF generator. The labeling is consistent with the valid requirements. They are made of the same materials, have identical indications and contraindications, and are used at the same site in the body. Some minor differences exist, such as the color of the PEEK handle and the connection type between parts. However, these variations do not impact safety or effectiveness. Biocompatibility, mechanical, and electrical tests were successfully completed for all products. Consequently, they are considered to be substantially equivalent.