August 26, 2026

Maquet Critical Care Ab
Jerker Åberg
Director Regulatory Affairs Maquet Critical Care AB
Röntgenvägen 2 Se-171 54
Solna, Sweden

Re: K253715
Trade/Device Name: Edi Catheter ENFit 6Fr/48 cm (6893166);
Edi Catheter ENFit 6Fr/49cm (6893273);
Edi Catheter ENFit 6Fr/50cm (6893274);
Edi Catheter ENFit 8Fr/50cm (6893275);
Edi Catheter ENFit 8Fr/100cm (6893276);
Edi Catheter ENFit 8Fr/125cm (6893277);
Edi Catheter ENFit 12Fr/125cm (6893278);
Edi Catheter ENFit 16Fr/125cm (6893279)
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube And Accessories
Regulatory Class: Class II
Product Code: PIF, CBK, MOD
Dated: July 24, 2026
Received: July 27, 2026

Dear Jerker Åberg:

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,

ANTHONY LEE -S

Anthony Lee, Ph.D., MBA
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity, and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology 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.	K253715

Please provide the device trade name(s).

Edi Catheter ENFit 6Fr/48 cm (6893166);
Edi Catheter ENFit 6Fr/49cm (6893273);
Edi Catheter ENFit 6Fr/50cm (6893274);
Edi Catheter ENFit 8Fr/50cm (6893275);
Edi Catheter ENFit 8Fr/100cm (6893276);
Edi Catheter ENFit 8Fr/125cm (6893277);
Edi Catheter ENFit 12Fr/125cm (6893278);
Edi Catheter ENFit 16Fr/125cm (6893279)

Please provide your Indications for Use below.

The Edi Catheter ENFit is intended for:
• administrating nutrition, fluids and medications via the naso-gastroenteric or oro-gastroenteric route
• aspiration via the naso-gastroenteric or oro-gastroenteric route
• transfer of electrical activity of the diaphragm (Edi signal) to compatible Servo ventilator systems on which neurally controlled ventilation modes are available.

Please select the types of uses.	☒ 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)

510(k) #: K253715

510(k) Summary

Prepared on: 2026-08-24

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Maquet Critical Care AB
Applicant Address	Röntgenvägen 2 SE-171 54, Solna, Sweden
Applicant Contact Telephone	+46 70 7827985
Applicant Contact	Mr. Jerker Åberg
Applicant Contact Email	jerker.aberg@getinge.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Edi Catheter ENFit 6Fr/48 cm (6893166); Edi Catheter ENFit 6Fr/49cm (6893273); Edi Catheter ENFit 6Fr/50cm (6893274); Edi Catheter ENFit 8Fr/50cm (6893275); Edi Catheter ENFit 8Fr/100cm (6893276); Edi Catheter ENFit 8Fr/125cm (6893277); Edi Catheter ENFit 12Fr/125cm (6893278); Edi Catheter ENFit 16Fr/125cm (6893279)
Common Name	Gastrointestinal Tube with Enteral Specific Connectors
Classification Name	Gastrointestinal Tube and Accessories
Regulation Number	21 CFR 876.5980
Product Code(s)	PIF, CBK, MOD

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K153688	Edi Catheter ENFit	PIF

Device Description Summary

21 CFR 807.92(a)(4)

The Edi Catheter ENFit is a nasogastric feeding tube with an array of electrodes that record diaphragm electrical activity (Edi). The Edi Catheter ENFit is an accessory to be used with Servo ventilator systems that have neurally controlled ventilation modes available. The Edi signal is used as an additional detector to improve the synchrony between the patient and the ventilator and to give the patient corresponding ventilatory support. The Edi Catheter ENFit may also be used to record and monitor diaphragm electrical activity while the Servo ventilator system is in standby.

The Edi Catheter ENFit has three functionalities:

1. To detect diaphragmatic electrical activity (Edi signals) by which the neurally ventilatory modes can be controlled.
2. To detect diaphragm electrical activity (Edi signals) by which the respiratory drive from the brain can be monitored even without ventilation, in stand-by mode.
3. To function as a naso-gastric tube for feeding and medications and to aspirate from the gastric ventricle.

The Edi Catheter ENFit is available in different sizes depending on the patient population. The Edi Catheter ENFit is for single-use only and may be used for up to five days. The catheter is sterilized by the use of gamma radiation and has a validated shelf-life of two years.

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

The Edi Catheter ENFit is intended for:
• administrating nutrition, fluids and medications via the naso-gastroenteric or oro-gastroenteric route
• aspiration via the naso-gastroenteric or oro-gastroenteric route
• transfer of electrical activity of the diaphragm (Edi signal) to compatible Servo ventilator systems on which neurally controlled ventilation modes are available.

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

The subject device Edi Catheter ENFit has the same indications for use as the predicate device Edi Catheter ENFit K152688. There is a slight clarification of the indications for use for the subject device, however not affecting directions for use or safety and effectiveness.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device Edi Catheter ENFit and the predicate device Edi Catheter ENFit (K153688) have the following similarities:
- The same intended use
- The same operating principles
- The same design
- The same sterilization method
- The same usage time of 5 days
- The same shelf life of 2 years

The subject device incorporates the following modifications:
• An additional shorter catheter version for premature patients, 6Fr/48cm with 2-lumen design
• Material change of the Male body of the ENFit connector
• Change of the sterile barrier of the packaging, the material in contact with the device remains unchanged

The design verification/validation testing demonstrates that the modification to the Edi Catheter ENFit has equivalent technological characteristics compared to the predicate devices, or in the case where differences are noted, such differences do not raise new questions of safety or effectiveness. Such conclusions are also supported by the successful design verification and validation conducted and included in the submission.

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

Testing was performed to demonstrate that the incorporated modifications do not affect the device's ability to perform as intended. Specifically, the objective of the testing was to confirm that the modifications do not compromise safety and performance.
The design verification activities consisted of:
• Product verification
• Tensile Strength
• Liquid Leakage
• Forces Tip to Tissue and Insertion/Withdrawal Force
• Horizontal Kinking
• Flow Rate
• Suction
• Resistance/Capacitance and Electrical Functionality
• Animal testing

ENFit Connector verification in accordance with ISO 80369-3, Small-bore connectors for liquids and gases in healthcare applications - Part 3: Connectors for enteral applications, using the test methods provided in ISO 80369-20, Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods.

Biocompatibility testing was conducted in accordance with ISO 10993-1, "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process" and applicable sub-standards.

Packaging validation was conducted in accordance with ISO 11607-1, "Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems" and ISO 11607-2, "Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes".

Sterilization validation was conducted in accordance with ISO 11137-1, "Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices" and applicable sub-standards.

Transport and storage testing was conducted in accordance with ASTM D4169, "Standard Practice for Performance Testing of Shipping Containers and System".

No clinical tests were conducted and submitted in this 510(k) submission.
The results of the verification/validation testing demonstrate that the Edi Catheter ENFit meets the established performance requirements for the device and that the proposed device is as safe and effective as the predicate device (K153688).