March 13, 2026

GIE Medical
% Gabriela Molnar
Regulatory Consultant
Rqm+
5000 Centregreen Way
Cary, North Carolina 27513

Re: K253987
Trade/Device Name: BARE Wireguided Balloon Dilation Catheter (1235)
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary Catheter And Accessories
Regulatory Class: Class II
Product Code: FGE
Dated: February 13, 2026
Received: February 13, 2026

Dear Gabriela Molnar:

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), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 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.
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.	K253987

Please provide the device trade name(s).

BARE Wireguided Balloon Dilation Catheter (1235)

Please provide your Indications for Use below.

The BARE Wireguided Balloon Dilation Catheter is indicated for use in adult and adolescent populations to endoscopically dilate strictures of the alimentary tract. Also indicated in adults for endoscopic dilation of the Sphincter of Oddi with or without prior sphincterotomy.

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)

510(k) SUMMARY

1 CONTACT DETAILS

Applicant	GIE Medical, Inc. 7601 Northland Drive N, Suite 170 Brooklyn Park, MN 55428 United States
Applicant Contact	Ian Schorn Telephone: 320-282-6312 Email: schorni@giemedical.com
Correspondent	RQM+ 5000 Centregreen Way, Suite 100 Cary, NC 27513 United States
Correspondent Contact	Gabriela Molnar, MS, RAC Regulatory Consultant Telephone: 612-859-4139 Email: gmolnar@rqmplus.com
510(k) #	K253987
Date Prepared	December 17, 2025

2 DEVICE NAME

Trade Name	BARE Wireguided Balloon Dilation Catheter
Common Name	Biliary catheter and accessories
Classification Name	Stents, Drains and Dilators for the Biliary Ducts
Regulation Number	876.5010
Product Code	FGE

3 LEGALLY MARKETED PREDICATE DEVICES

Predicate #	**Predicate Trade Name**	**Product Code**
K112994	CRE Wireguided Balloon Dilatation Catheter	FGE
K180418 (Reference)	Reliant Multistage Dilatation Balloon Catheter	FGE, KNQ

4 DEVICE DESCRIPTION SUMMARY

The BARE Wireguided Balloon Dilation Catheter is an over-the-wire, through the scope, dual lumen balloon catheter compatible with 0.035” guidewires with a distally mounted semi-compliant inflatable balloon and an atraumatic tapered tip. The multistage balloon provides three distinct diameters at three corresponding pressures. The device has two radiopaque marker bands, visible under fluoroscopy, to aid in balloon positioning.

The BARE Wireguided Balloon Dilation Catheter is available in multiple balloon diameters and balloon lengths with a catheter shaft length of 180 cm or 240 cm. A balloon compliance chart with inflation pressures and balloon diameters is located on the foil pouch label and on the information tag attached to the catheter shaft.

5 INTENDED USE/INDICATIONS FOR USE

The BARE Wireguided Balloon Dilation Catheter is indicated for use in adult and adolescent populations to endoscopically dilate strictures of the alimentary tract. Also indicated in adults for endoscopic dilation of the Sphincter of Oddi with or without prior sphincterotomy.

6 INDICATIONS FOR USE COMPARISON

The subject device and predicate device have the same indications for use.

7 TECHNOLOGICAL COMPARISON

The subject device is similar to the predicate device in terms of design, materials, and principles of operation. Both devices are single-use dual lumen catheters (guidewire lumen and inflation lumen) with a 3-stage balloon that are delivered through an endoscope for dilation of the alimentary tract. While there are minor differences in design, bench testing has demonstrated substantial equivalence.

8 NON-CLINICAL SUMMARY AND CONCLUSIONS

A series of nonclinical tests were conducted on the device to ensure product specifications were met and to determine suitability of device performance for its intended use. Mechanical testing included:

- Dimensional (Crossing Profile, Stricture Entry Profile, Catheter Working Length, Balloon Length, Balloon Diameter)
- Balloon Compliance Curve and Rated Burst Pressure
- Balloon Fatigue
- Inflate/Deflate Time
- Marker Band Location and Spacing
- Luer Hub Leakage and Compatibility
- Tensile Strength (catheter tip, balloon bonds, and luer hub bond)
- Kink Resistance
- Guidewire and Endoscope Compatibility

Additional non-clinical testing included packaging testing on aged and non-aged product, sterilization validation per ISO 11135:2014 and biocompatibility testing per ISO 10993-1:2018.

The BARE Wireguided Balloon Dilation Catheter underwent non-clinical testing to meet design requirements similar to the predicate device. Non-clinical testing showed design input requirements were met demonstrating that the device is as safe, effective, and performs as well as the legally marketed device.