April 16, 2026

Medi-Globe GmbH
Stephan Schneider
Head of Regulatory Affairs
Medi-Globe Str. 1-5
Achenmuehle, BY 83101
Germany

Re: K251658
Trade/Device Name: Endoflux™ Biliary & Pancreatic Stent Sets
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary Catheter And Accessories
Regulatory Class: Class II
Product Code: FGE
Dated: July 23, 2025
Received: July 23, 2025

Dear Stephan Schneider:

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

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)*
K251658

Device Name
Endoflux™ Biliary & Pancreatic Stent Sets

Indications for Use *(Describe)*
Biliary Stents/Stent sets are used to drain obstructed biliary ducts Pancreatic Stents/Stent sets are used to drain obstructed pancreatic ducts Guiding Catheters, Pushers, and Stent Introducer Sets are used for endoscopic biliary and pancreatic stent placement

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.

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510(k) #: K251658

510(k) Summary

Prepared on: 2026-03-18

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Medi-Globe GmbH
Applicant Address	Medi-Globe Str. 1-5 Achenmuehle BY 83101 Germany
Applicant Contact Telephone	+498032973274
Applicant Contact	Mr. Stephan Schneider
Applicant Contact Email	schneider@medi-globe.de

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Endoflux™ Biliary & Pancreatic Stent Sets
Common Name	Biliary catheter and accessories
Classification Name	Stents, Drains And Dilators For The Biliary Ducts
Regulation Number	876.5010
Product Code(s)	FGE

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K172044	Cotton-Huibregtse® Biliary Stent, Cotton-Leung® Biliary Stent, Cotton- Leung® Sof-Flex® Biliary Stent, ST-2 Soehendra Tannenbaum® Biliary Stent, Zimmon® Biliary Stent, Cotton-Huibregtse® Biliary Stent Set, Cotton- Leung® Biliary Stent Set, Zimmon® Biliary Stent Set, Solus® Double Pigtail Stent with Introducer, Guiding Catheter, Pushing Catheter, Fusion® Pushing Catheter, Stent Introducer Set, Oasis® One Action Stent Introduction System, Fusion® Oasis® One Action Stent Introduction System, Oasis® One Action Stent Introduction System with preloaded Cotton-Leung® Biliary Stent, Oasis® One Action Stent Introduction System with preloaded ST-2 Tannenbaum® Biliary Stent.	FGE
K172057	Zimmon® Pancreatic Stent/Stent sets, Geenen® Pancreatic Stents/Stent Sets, Johlin® Pancreatic Wedge Stent and Introducer, Guiding Catheter and Pushing Catheter	FGE

Device Description Summary

21 CFR 807.92(a)(4)

The intended use of all Medi-Globe Endoflux™ Biliary & Pancreatic Stent Sets is to drain obstructed biliary or pancreatic ducts. A variety of stents in different sizes are available across the device range to accommodate various patient anatomies, the size and location of the obstruction and physician preference. They are offered in French sizes of between 5 Fr and 11.5 Fr, and in labelled lengths of between 2 cm and 18 cm. The subject devices and their components can be supplied as stent only, introducer only (Guiding Catheter, Pusher), Stent Introducer Set (Guiding Catheter and Pusher) or as stent sets combining stent and introducers/Stent Introducer Sets.

The stent sets can contain one or several of the following stent placement components; a flap protector, a Guiding Catheter, a Pusher, or a Stent Introducer Set. The flap protector can be provided to aid in the introduction of the device over the wire and introduced into the working channel of the endoscope. The function of the Guiding Catheter is to guide the stent as part of its introduction to its intended location. The Guiding Catheter also has a hub that allows for contrast injection. The function of the Pusher is to advance the stent, over a pre-positioned wire guide or Guiding Catheter, to its intended location within the anatomy, and to maintain the position of the Stent as it being deployed. Some introducers / Stent Introducer Sets have a port that will allow use of the device in a short wire configuration. The stents are polymeric and include radiopaque material. The stent designs include bent shapes and anti-migration features such as pigtails and flaps. Side-ports on the stents assist in drainage. All stents are deployed endoscopically over a guide wire in the same manner under fluoroscopic and endoscopic monitoring.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Biliary Stents/Stent sets are used to drain obstructed biliary ducts
Pancreatic Stents/Stent sets are used to drain obstructed pancreatic ducts
Guiding Catheters, Pushers, and Stent Introducer Sets are used for endoscopic biliary and pancreatic stent placement

Indications for Use Comparison

21 CFR 807.92(a)(5)

Indications for use are the same

Technological Comparison

21 CFR 807.92(a)(6)

The subject device is substantially equivalent to the currently marketed devices, Cook Biliary Stents/Stent Sets, cleared under K172044 on February 27th, 2018, and Cook Pancreatic Stents/Stent Sets, cleared under K172057 on March 9th, 2018.
The similarities between the predicate devices and subject devices can be summarized as follows:
• The subject devices and predicate devices are for use in the biliary or pancreatic duct.
• The subject devices and predicate devices have the same intended use
o Biliary Stents/Stent sets are used to drain obstructed biliary ducts
o Pancreatic Stents/Stent sets are used to drain obstructed pancreatic ducts
o Guiding Catheters, Pushers, and Stent Introducer Sets are used for endoscopic biliary and pancreatic stent placement
• The subject devices and predicate devices are intended for single use only.
• The subject devices and predicate devices are supplied sterile
• The subject devices and predicate devices are sterilized using ethylene oxide.
• The subject devices and predicate devices are for professional use only.
• The subject devices and predicate devices require a guide wire and endoscope to perform the therapeutic procedure.
• The subject devices and predicate devices are placed within the body endoscopically using fluoroscopic monitoring.
Stent and stent sets
• Stent shape is common with some subject devices and the predicate devices.
• The subject devices and the predicate devices have anti migration features.
• The subject devices and the predicate devices have stent loading aids.
• Side port features are present on many of the subject devices and the predicate devices to support additional drainage.
• The subject devices and predicate devices are visible under fluoroscopy – stent material is radiopaque.
• The subject devices and predicate devices have the common stent set components –stent, introducer or introduction system and stent loading aid.
• Many of the subject devices and the predicate devices share the same material of composition.
• The subject devices and predicate devices have common stent diameter sizes.
• The subject devices and predicate devices have common stent lengths.
Introducers and Introduction systems
• Radiopaque bands are present on guiding catheter component of subject devices and predicate devices.
• Subject device introducers and introduction systems and predicate devices have the similar components – guiding catheter, pusher
• The pusher component of the subject devices and the pusher of predicate devices have common diameter size and lengths.
• The guiding catheter component of the subject devices and the guiding catheter of the predicate device have common diameter sizes and lengths.
Differences between the predicate devices and subject devices can be summarized as follows:
• Stent shape and anti-migration features.
• Drainage features
• Variations in introducer and introduction system components supplied.
• Variations in stent set components supplied.
• Variations in introducer materials.
• Variations in stent materials.
• Variations in stent loading aids

• Introducer/introduction system dimensions
• Stent dimensions.
There is no change to the safety or effectiveness of these subject devices when compared to the cleared predicate devices. Design validation and verifications activities (performance testing) performed support the performance, safety and effectiveness of these subject devices and demonstrate no change in the safety and effectiveness profile previously established with the predicate device.

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

The biocompatibility evaluation for the Medi-Globe Biliary & Pancreatic Stent Sets devices, Stents, and Introducers was conducted in accordance with ISO 10993-1:2018 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process" and FDA's biocompatibility guidance, Use of International Standard ISO-10993-1, "Biological Evaluation of Medical Device - Part 1: Evaluation and Testing within a risk management process" (September 8, 2023).

Testing was completed to Medi-Globe's design control system. Performance testing included simulated use, dimensional and visual testing, tensile strength testing, MRI conditional testing, radiopacity, flow rate and shelf-life testing.

Not Applicable

The subject device has indications for use and technological characteristics that are similar to the predicate device. The results of the non-clinical testing demonstrate that the Medi-Globe Biliary & Pancreatic Stent Sets devices, Stents, and Introducers met the design input requirements based on the intended use, and do not raise new questions of safety or effectiveness. The results of these tests support a determination of substantial equivalence of the Medi-Globe Biliary & Pancreatic Stent Sets devices, Stents, and Introducers to the predicate devices.