April 3, 2023

G-Flex Europe SPRL
Thierry Cremer
QA & RA Manager
20, Rue de l'industrie
Nivelles, Brabant Wallon 1400
BELGIUM

Re: K222006
Trade/Device Name: Sclerotherapy & Endoscopic Needles
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FBK
Dated: February 22, 2023
Received: February 27, 2023

Dear Thierry Cremer:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Shanil P. Haugen -S

Shanil P. Haugen, 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

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)*
K222006

Device Name
Sclerotherapy & Endoscopic Needles

Indications for Use *(Describe)*
Sclerotherapy & Endoscopic Needles are endoscopic accessories intended to introduce a sclerosing agent, vasoconstrictor, or other solutions into selected sites to control actual or potential bleeding lesions in the digestive system or to inject liquid to aid in polypectomy procedures.

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.

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510(K) SUMMARY

1. SUBMITTER

Submitter Name:	G-Flex Europe SPRL
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Contact Person:	Thierry CREMER, QA & RA Manager
Email:	thierry@g-flex.com
Date Prepared:	March 10, 2022

2. DEVICE

Device Trade Name:	Sclerotherapy & Endoscopic Needles
Common Name:	Endoscopic accessory
Classification Name:	Endoscope and Accessories
Regulation Number:	876.1500
Product Code:	FBK
Class:	2
Classification Panel:	Gastroenterology/Urology

3. PREDICATE DEVICE

Primary Predicate Device: Boston Scientific, Interject Injection Therapy Needle Catheter (K171454).

4. DEVICE DESCRIPTION

Sclerotherapy & Endoscopic Needles are endoscopic accessories intended to introduce a sclerosing agent, vasoconstrictor, or other solutions into selected sites to control actual or potential bleeding lesions in the digestive system or to inject liquid to aid in polypectomy procedures.

Sclerotherapy & Endoscopic Needles (see schematic representation in Figure 1) are made of a flexible catheter with an inner tube connected to the needle at the distal end and a handle with a piston and a luer-lock connection at the proximal end.

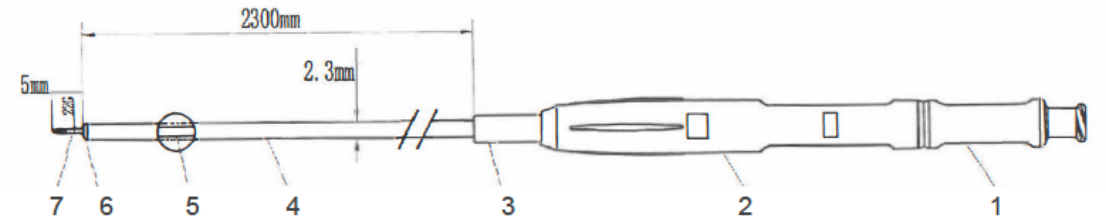

Figure 1 - Schematic representation of Sclerotherapy & Endoscopic Needles.
(1 Back handle, 2 Front handle, 3 Protective sleeve, 4 Outer tube, 5 Inner tube, 6 Guiding head, 7 Needle.)

All devices of this family group are packed in a medical grade paper pouch and sterilized by ETO. The sterile devices are distributed in carton boxes along with an Instruction for Use.

There are 4 variations of the Sclerotherapy & Endoscopic Needles with different catheter lengths and diameters and different needle lengths and diameters (see Table 1).

Table 1 - Different models of Sclerotherapy & Endoscopic Needles.

Reference	Catheter dimensions		Needle dimensions	
	Length (cm)	Diameter (mm)	Length (mm)	Diameter (mm)
GF252202	180	2.3	5	0.7 (22 GA)
GF252203	230	2.3	5	0.7 (22GA)
GF262302	180	2.3	5	1.0 (19 GA)
GF252203-25	230	2.3	5	0.5 (25 GA)

The device is used through an endoscope to inject different types of sclerosing agents, vasoconstrictors, or other solutions into selected sites of the digestive system to control actual or potential bleeding. It can be also used to inject liquid into the mucosa to aid in polypectomy procedures.

These procedures can last from 15 minutes to 30 minutes. Furthermore, this device comes in contact with the digestive system mucosa.

There are no accessories for this kind of devices.

5. INDICATIONS FOR USE

Sclerotherapy & Endoscopic Needles are endoscopic accessories intended to introduce a sclerosing agent, vasoconstrictor, or other solutions into selected sites to control actual or potential bleeding lesions in the digestive system or to inject liquid to aid in polypectomy procedures.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

The comparison chart below provides evidence to facilitate the substantial equivalence determination between the Sclerotherapy & Endoscopic Needles to the predicate device (K171454) with respect to intended use, technological characteristics and principles of operation.

Feature	Proposed Device	Primary Predicate Device	Assessment of Equivalence
Device name	Sclerotherapy & Endoscopic Needles	Interject Injection Therapy Needle Catheter	NA
510(k) Number	K222006	K171454	NA
Manufacturer	G-Flex Europe SPRL	Boston Scientific	NA
Regulation Number	876.1500	876.1500	Fully similar
Device Classification Name	Endoscopic Injection Needle, Gastroenterology-Urology	Endoscopic Injection Needle, Gastroenterology-Urology	Fully similar
Product Code	FBK	FBK	Fully similar
Clinical Condition	Treatment of varices in the human digestive tract.	Treatment of varices in the human digestive tract.	Fully similar
Intended Use/ Indications for use	Sclerotherapy & Endoscopic Needles are endoscopic accessories intended to introduce a sclerosing agent, vasoconstrictor, or other solutions into selected sites to control actual or potential	The Interject Injection Therapy Needle Catheter is used for endoscopic injection into gastrointestinal mucosa and submucosa to: • Introduce a sclerosing agent, vasoconstrictor, or other	Similar

Feature	Proposed Device	Primary Predicate Device	Assessment of Equivalence
	bleeding lesions in the digestive system or to inject liquid to aid in polypectomy procedures.	solutions into selected sites to control actual or potential bleeding lesions in the digestive system • Aid in Endoscopic Mucosal Resection (EMR), Endoscopic Submucosal Dissection (ESD), or polypectomy procedures • Control non-variceal hemorrhage	
Contra-indications	Patients with lesions inappropriate for injection therapy.	Contraindications for this device are those applicable to injection therapy and include, but may not be limited to, those patients allergic to sclerosing or vasoconstriction agents and patients with lesions inappropriate for injection therapy with sclerosing or vasoconstriction agents.	Similar
Site of use	Gastrointestinal tract	Gastrointestinal tract	Fully similar
Duration of contact	Less than 60 minutes	Less than 60 minutes	Fully similar
Intended patient population	Patients who have (potential) bleeding lesions in the digestive system.	Patients who have (potential) bleeding lesions in the digestive system.	Fully similar
Design	Needle + Catheter + Handle	Needle + Catheter + Handle	Fully similar
Conditions of use	Single Use	Single Use	Fully similar
Environment of use	Hospitals or clinics	Hospitals or clinics	Fully similar
Catheter length (cm)	180 230	200 240	Similar
Sheath outer diameter (mm)	2.3	1.8 2.3	Similar
Needle length (mm)	5	4 6	Similar
Needle diameter (mm)	0.5 (25 GA) 0.7 (22GA) 1.0 (19 GA)	0.51 0.64	Similar
Needle material	Stainless steel	Stainless steel	Fully similar
Sterilization	Ethylene oxide ISO 11135	Ethylene oxide ISO 11135	Fully similar
Biological evaluation	ISO 10993-1 ISO 10993-7	ISO 10993-1 ISO 10993-7	Fully similar

Equivalence:

The Sclerotherapy & Endoscopic Needles are comparable to the predicate device with similar technological characteristics and intended use, specifically to perform electrosurgical procedures through an endoscope. The Sclerotherapy & Endoscopic Needles thus meet the requirements for 510(k) substantial equivalence.

Differences that are demonstrated to be substantially equivalent:

As indicated in the table above, several differences were identified between the Sclerotherapy & Endoscopic Needles and the primary predicate, namely the general wording of the indications for use and of the contraindications and the dimensions of the devices. While the wording of the indications for use and of the contraindications differs slightly between the proposed and predicate devices, this does not reflect any difference in the intended use and clinical application of the Sclerotherapy & Endoscopic Needles which are strictly identical to the predicate. The differences in dimensions are minor and, once again, do not impact the clinical application of the proposed device compared to the predicate.

Performance testing was conducted to demonstrate substantial equivalence of the Sclerotherapy & Endoscopic Needles to the predicate device. The test results are summarized below.

7. NON-CLINICAL PERFORMANCE DATA

Bench testing	The Sclerotherapy & Endoscopic Needles were subjected to bench tests including dimensions verification, visual inspection, mechanical evaluation, controllability, permeability and smoothness. Results demonstrate that the device meets the design specifications
Biocompatibility	The Sclerotherapy & Endoscopic Needles were the subject of a range of biocompatibility tests in accordance with ISO 10993 series. Test results confirmed that the device is biocompatible for the stated intended use.
Sterility	The Sclerotherapy & Endoscopic Needles are provided sterile and are sterilized by ethylene oxide to meet a minimum sterility assurance level (SAL) of 10^{-6}. Validation of the sterilization dose was conducted following the half-cycle method I, in accordance with ISO 11135-1:2014 and ISO 11138-2:2009.
Shelf-life	3-year accelerated and 2-year real time ageing validations were performed to demonstrate that the dimensions, mechanical resistance, controllability, permeability, thoroughness, bio-property and sterility were not affected during the stated shelf-life of the device. A 3-year real time ageing validation is ongoing.

Validation studies for sterilization, packaging and shelf-life conform to the following standard:

Standard reference	Standard title
ISO 11607-1:2019	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11135-1:2014	Sterilization of health care products - Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
ASTM F1980-16	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ASTM D4169-16	Standard Practice for Performance Testing of Shipping Containers and Systems

8. CLINICAL PERFORMANCE DATA

No clinical testing was performed to support the medical device as the indications for use are equivalent to the predicate device. Additionally, endoscopic accessories such as the proposed and predicate devices have been on the market for many years and their use has been safe and effective.

9. CONCLUSION

The information discussed above and provided in this 510(k) submission demonstrates that the Sclerotherapy & Endoscopic Needles devices are substantially equivalent to the predicate device and that they are as safe and effective for the patients.