June 9, 2022

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

Re: K211909
Trade/Device Name: Cysto-Gastro-Sets
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: Class II
Product Code: KNS
Dated: May 2, 2022
Received: May 4, 2022

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,

Je Hi An, 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)*
K211909

Device Name
Cysto-Gastro Sets

Indications for Use *(Describe)*
Cysto-Gastro Sets are intended to be used to electrosurgically cannulate pancreatic pseudo-cysts endoscopically (via the transgastric or transduodenal wall) as an alternative to surgical or percutaneous treatment.

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.

510(K) SUMMARY

1. SUBMITTER

Submitter Name:	G-Flex Europe SPRL
Submitter Address:	20, Rue de l'industrie 1400 Nivelles Belgium
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Contact Person:	Thierry CREMER, QA & RA Manager
Email:	thierry@g-flex.com
Date Prepared:	June 3, 2021

2. DEVICE

Device Trade Name:	Cysto-Gastro Sets
Common Name:	Endoscopic electrosurgery device
Classification Name:	Endoscopic electrosurgical unit and accessories
Regulation Number:	876.4300
Product Code:	KNS
Class:	2
Classification Panel:	Gastroenterology/Urology

3. PREDICATE DEVICE

Primary Predicate Device: Wilson-Cook Cystotome (K022595).

4. DEVICE DESCRIPTION

Cysto-Gastro Sets are intended to be used to electrosurgically cannulate pancreatic pseudocysts endoscopically (via the transgastric or transduodenal wall) as an alternative to surgical or percutaneous treatment.

Each device is made of an outer flexible Teflon tube equipped with a metal tip at the distal end and an HF (high frequency) connector at the proximal end. Some models included an inner Teflon sheet that slides inside the outer sheet and are equipped with an HF needle at the distal tip and an HF connector at the proximal end.

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 5 variations of the Cysto-Gastro Sets with different catheter length and diameter, with or without HF needle. However, all variations are delivered sterile and intended for single use.

Variety of Cysto-Gastro Sets are described in the table below. The main difference between models is the presence or not of the HF needle, which gives the Cysto-Gastro Sets the possibility to perforate the tissue with the needle before enlarging the hole with the diathermic bigger tip. The other variation is the diameter which will define the final size of the perforation and ultimately the size of the stent that will be used in the next procedure. All devices of this family group are sterile by ETO and intended for single use:

Reference	**Dimensions**			
	Length (cm)	**Diameter (Fr)**	**Details**	
CYSTO06U	180	6	Without HF Needle	Single Use

CYSTO08UK	210	8.5	With HF Needle	Single Use
CYSTO10U	180	10	Without HF Needle	Single Use
CYSTO10UK	210	10	With HF Needle	Single Use
CYSTO85U	180	8.5	Without HF Needle	Single Use

5. INDICATIONS FOR USE

Cysto-Gastro Sets are intended to be used to electrosurgically cannulate pancreatic pseudocysts endoscopically (via the transgastric or transduodenal wall) as an alternative to surgical or percutaneous treatment.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

The comparison chart below provides evidence to facilitate the substantial equivalence determination between the Cysto-Gastro Sets to the predicate device (K022595) with respect to intended use, technological characteristics and principles of operation.

Feature	Proposed Device	Primary Predicate Device	Assessment of Equivalence
Device name	Cysto-Gastro Sets	Cystotome	NA
510(k) Number	K211909	K022595	NA
Manufacturer	G-Flex Europe SPRL	Wilson-Cook Medical Inc	NA
Regulation Number	876.4300	876.4300	Fully similar
Device Classification Name	Endoscopic electrosurgical unit and accessories	Endoscopic electrosurgical unit and accessories	Fully similar
Product Code	KNS	KNS	Fully similar
Clinical Condition	For electrosurgical puncture of the transgastric or transduodenal wall and into pancreatic pseudocysts	For electrosurgical puncture of the transgastric or transduodenal wall and into pancreatic pseudocysts	Fully similar
Intended Use/ Indications for use	Cysto-Gastro Sets are intended to be used to electrosurgically cannulate pancreatic pseudocysts endoscopically (via the transgastric or transduodenal wall) as an alternative to surgical or percutaneous treatment.	This device is designed to electrosurgically puncture a hole in the transgastric or transduodenal wall and into a pancreatic pseudocyst, when it is visibly bulging into the gastrointestinal tract.	Fully similar
Contra-indications	Contraindications include blood coagulation diseases, interposing vessels, nickel sensitivity, and contraindications related to the use of electrical scalpel. Cysto-Gastro Sets are not recommended to be used on pancreatic pseudocysts that are less than 4cm in diameter similar.	Contraindications include those specific to blood coagulation disease, interposing vessels between the pseudocyst wall and that of the stomach or the duodenum. If the pseudocyst is <4 cm in diameter do not proceed.	Similar, the safety and effectiveness are not impacted. Nickel sensitivity is included as a warning in the predicate device.
Site of use	Endoscopic pancreatic pseudocyst	Endoscopic pancreatic pseudocyst	Fully similar

Feature	Proposed Device	Primary Predicate Device	Assessment of Equivalence
Intended patient population	Patients who are subject to endoscopic puncture of pancreatic pseudocyst	Patients who are subject to endoscopic puncture of pancreatic pseudocyst	Fully similar
Performances	Effective puncture of the pseudocyst	Effective puncture of the pseudocyst	Fully similar
Design	Diameter: 6, 8,5 or 10 Fr Length: 180 or 210 cm External form: diathermic ring + needle (depending on the model) + catheter + handle with electrode Needle design: Needle knife	Diameter: 10 Fr Length: 190 cm External form: diathermic ring + needle + catheter + electrode Needle design: Needle knife	Similar, the variations (diameter, length, absence of the needle depending on the model) do not affect the safety or effectiveness of the proposed device.
Conditions of use	Single Use	Single Use	Fully similar
Sterilization mode	ETO	ETO	Fully similar
Operation and clinical performance	Introduction of the device in the endoscope and puncture of the pseudocyst following endoscopic procedure. Performance: Effective puncture of the pseudocyst	Introduction of the device in the endoscope and puncture of the pseudocyst following endoscopic procedure. Performance: Effective puncture of the pseudocyst	Fully similar
Recommended size guide	0,035 inch	0,035 inch	Fully similar
Materials	Stainless Steel (needle) / teflon (catheter) / POM + MABS (handle)	Needle: stainless steel	Fully similar
Tissues or body fluids in contact	Tissues near the cyst in contact with the needle	Tissues near the cyst in contact with the needle	Fully similar
Duration of contact	Limited exposure (<24h)	Limited exposure (<24h)	Fully similar
Type of body-device interaction	Invasive	Invasive	Fully similar

The Cysto-Gastro Sets is comparable to predicate device with similar technological characteristics and intended use, specifically to perform electrosurgical procedures through an endoscope. The Cysto-Gastro Sets thus meets the requirements for 510(k) substantial equivalence.

As indicated in the table above, several differences were identified between the Cysto-Gastro Sets and the primary predicate, namely the contraindications, diameter, length and absence of the needle depending on the model. Performance testing was conducted to demonstrate substantial equivalence of the Cysto-Gastro Sets to the predicate device. The test results are summarized below.

7. NON-CLINICAL PERFORMANCE DATA

Bench testing

The Cysto-Gastro Sets was subjected to bench tests including visual inspection, dimensions verification, simulated use, leaks, flow rate, corrosion resistance, X-ray visibility and mechanical. Results demonstrate that the device meets the design specifications. Additionally, the Cysto-Gastro Sets meets the design specifications and the requirements of the relevant

standards for safety and performance of HF electrosurgical equipment (IEC 60601-2-2).

Biocompatibility — The Cysto-Gastro Sets was the subject of a range of biocompatibility tests in accordance with ISO 10993 series. Test results confirmed that the Cysto-Gastro Sets is biocompatible for the stated intended use.

Sterilization — The Cysto-Gastro Sets is provided sterile and is intended for single patient use only. The Cysto-Gastro Sets is sterilized by ETO to meet a minimum sterility assurance level (SAL) of 10^{-6}.

Shelf-life — Shelf-life study supports a shelf life of 3 years for The Cysto-Gastro Sets when stored under the recommended environmental conditions. The shelf-life studies confirmed that the packaging maintains the integrity of the device and its sterility throughout the shelf life of the device.

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 11607-2:2019	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
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
ANSI AAMI ISO 11737-1:2018 14-514	Sterilization Of Health Care Products – Microbiological Methods -- Part 1: Determination Of A Population Of Microorganisms On Products
ASTM D7386-16	Standard Practice for Performance Testing of Packages for Single Parcel Delivery Systems
ASTM F1929-15	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration

8. CLINICAL PERFORMANCE DATA

No clinical testing was performed.

9. CONCLUSION

The information discussed above and provided in this 510(k) submission demonstrates that the Cysto-Gastro Sets device is substantially equivalent to the predicate.