September 21, 2023

S&G Biotech Inc.
Mr. Dave Kim
Official Correspondent
7505 Fannin St. Suite 610
Houston, Texas 77054

Re: K223354
Trade/Device Name: EGIS Biliary Single Bare Stent
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary Catheter And Accessories
Regulatory Class: Class II
Product Code: FGE
Dated: August 18, 2023
Received: August 18, 2023

Dear Mr. Dave Kim:

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 and the limitations described below. 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.

The OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section

513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

The safety and effectiveness of this device for use in the vascular system has not been established.

Furthermore, the indication for biliary use use must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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,

Kellie B. Kelm -S

for
Courtney H. Lias, Ph.D.
Director
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)*
K223354

Device Name

EGIS Biliary Single Bare Stent

Indications for Use *(Describe)*

The EGIS Biliary Single Bare Stent is indicated for the palliation of malignant strictures in the biliary tree.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary K223354

The following 510(k) summary is being submitted as required by 21 CFR Part 807.92;

5.1 Submitter: S&G BIOTECH INC.
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Contact Person: (Official Correspondent) Mr. Dave Kim
7505 Fannin St. Suite 610, Houston, TX 77054
Tel: 713-467-2607
Email: davekim@mtech-inc.net

Date Prepared: December 28, 2022

5.2 Device Identification

Device Trade Name	EGIS Biliary Single Bare Stent
Common Name	Biliary catheter and accessories
Classification Name, Number	Biliary catheter and accessories (21 CFR 876.5010)
Device Classification	II
Product Code	FGE

5.3 Predicated or legally marketed devices which are substantially equivalent

Predicated device: K111149, "HANAROSTENT Biliary (NNN)", manufactured by "M.I.Tech"

5.4 Device Description

Single bare stent has straight and round cylinder form made of a Nitinol wire. It is woven twice in V-hook type by one wire. The cell size is approximately 2 mm. The end of wire is tied by the both wires. No bonding material is used. Single bare Stent is manufactured by continuous works, V and Twist structure manufacturing process. From these processes, design of Single bare stent has the 12 bends and 2mm cell size. 2mm cell size has the merit to prolong the time that tissue grows up into the stent. In addition, Single Bare Stent designed to have the Radial force, Flexibility and conformability. Single Bare Stent has 6 markers in diameter 6, 7, and 8mm in size and 8 markers in diameter 10mm in size; 2 or 3 markers at both sides and 2 markers at the center. Markers are made of Gold-plated Tungsten wire. They are intended to identify the location of the loaded stent through X-ray.

5.5 Statement of Indication for use

The EGIS Biliary Single Bare Stent is indicated for the palliation of malignant strictures in the biliary tree.

5.6 Non-clinical Test Conclusion

The following properties were tested based on the referenced standards. All the test results support substantial equivalence to the predicate devices.

- Shelf- Life Test

- ISO 10993-3- Genotocixity (Ames test) & Genotocixity (chromosomal aberration)
- ISO 10993-4- Haemolysis
- ISO 10993-5- Cytotoxicity
- ISO 10993-6- Implantation
- ISO 10993-10 - Sensitization & Intracutatneous Reactivity
- ISO 10993-11 – Acute systemic toxicity & Subchronic Toxicity & Pyrogens
- Other bench testing- Foreshortening, Stent integrity, Dimensional Verification, Radial Compression Force, Radial Outward Force, Pitting Corrosion, Corrosion, Crossin Profile, Deployment, Catheter Bond Strength, Radiopacity, MR

Bench test results allowed to conclude that EGIS Biliary Single Bare Stent is substantially equivalent to the predicate devices for its intended use.

5.7 Clinical Test Conclusion

Clinical testing was not required for this submission.

5.8 Technical Characteristics and Substantial Equivalence

The EGIS Biliary Single Bare Stent is substantially equivalent to HANAROSTENT Biliary (NNN) (K111149). The following comparison table is presented to demonstrate substantial equivalence. The EGIS Biliary Single Bare Stent does not have a new intended use. It shows equivalent specifications with the predicate devices in most of the parameters. However, there are no significant differences in some parameters [Stent's Diameter, Stent's Length, Deployment System's Diameter, Deployment System's Usable Length, Delivery Deployment and withdrawal, Radial Outward Force, Compression Force(Radial Compression Force), Dimensional Verification, Corrosion, Pitting corrosion, Catheter Bond strength, Foreshortening] between the EGIS Biliary Single Bare Stent and Predicate Device[HANAROSTENT Biliary (NNN) (K111149)].

Table 1. General Device Characteristics Comparison Table

	Candidate Device	**Predicate Device**	**Substantial Equivalence Analysis**
510(k) Number	K223354	K111149	-
Device Name	EGIS Biliary Single Bare Stent	HANAROSTENT Biliary (NNN)	-
Common Name	Biliary catheter and accessories	Biliary catheter and accessories	-
Manufacturer	S&G BIOTECH INC.	M.I.Tech	-
Indication for Use	The EGIS Biliary Single Bare Stent s indicated for the palliation of malignant strictures in the biliary tree	The HANAROSTENT® Biliary (NNN) is indicated for the palliation of malignant strictures in the biliary tree	Same as predicate
Stent's Type	Uncovered Type	Uncovered Type	Same as predicate
Stent's Diameter	6mm & 7mm & 8 mm & 10 mm	8mm & 10mm	No significant difference
Stent's Length	30mm & 40 mm & 50 mm & 60 mm & 70 mm & 80 mm & 90 mm & 100 mm & 120 mm	40 mm & 50 mm & 60 mm & 70 mm & 80 mm & 90 mm & 100 mm & 120 mm	No significant difference
Deployment System's Diameter	2mm(6F), 2.7 mm (8Fr)	2.36mm	No significant difference

Deployment System's Usable Length	500 mm & 1800 mm	600mm & 1800mm	No significant difference
Single use	Yes	Yes	Same as predicate
Radiopaque Markers	Yes	Yes	Same as predicate
Lasso	No	No	Same as predicate
Delivery, Deployment, and Withdrawal	Deploy force: 8.6 ~ 18.8N Distance: 0.13 ~ 1.95mm	Deploy force: 6.3 ~ 14.2 N Distance: 0.36 ~ 4.37mm	No significant difference
Radial Outward Force	1.04 ~ 1.28 N	0.64 ~ 1.01 N	No significant difference
Compression Force (Radial Compression Force)	1.03 ~ 1.27 N	0.66 ~ 1.05 N	No significant difference
Dimensional Verification	1.39 ~ 2.46 %	0.98 ~ 2.93%	No significant difference
Corrosion	0.95 ~ 1.29 N	0.67 ~ 1.05 N	No significant difference
Pitting corrosion	1.00 ~ 1.03 N	0.75 ~ 0.80 N	No significant difference
Catheter bond strength	Sheath hub & tube (A) : 52.5 ~ 68.9 N Peek tube & Olive Tip (B): 20.7 ~ 38.5 N Pusher hub & tube (C): 168.9 ~ 520.0 N Stainless steel & PP tube (D): 24.2 ~ 77.7 N	Sheath hub & tube (A) : 51.3 ~ 65.8 N Peek tube & Olive Tip (B): 14.5 ~ 20.6 N Pusher hub & tube (C): more than 500 N Stainless steel & PP tube (D): 32.2 ~ 39.3 N	No significant difference
Foreshortening	31.4 ~ 36.9 %	17.6~ 21.5%	No significant difference
Target Population	Patients in need of treatment of malignant biliary strictures	Patients in need of treatment of malignant biliary strictures	Same as predicate
Anatomical Site	Bile duct	Bile duct	Same as predicate
Sterilization Method	EO Gas Sterilization	EO gas sterilization	Same as predicate
Packaging Material	Tyvek, Manila paper	Tyvek, paper box	Same as predicate
Bio-compatibility	All user directly contacting materials are compliance with ISO10993 requirements.	All user directly contacting materials are compliance with ISO10993 requirements.	Same as predicate

Although the subject device and predicate device are no significant differences in some parameters, the differences do not affect the substantial equivalence of the subject device when compared to the predicate device.

5.9 Conclusion

Based on the testing results, S&G BIOTECH INC. concludes that the subject device is substantially equivalent to the predicate device.