June 25, 2025

S&G Biotech Inc.
% Dave Kim
Regulatory Affairs Consultant
Mtech Group LLC
7505 Fannin St Suite 610
Houston, Texas 77054

Re: K242845
Trade/Device Name: EGIS Biliary Double Bare Stent (BDB080405)
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary Catheter And Accessories
Regulatory Class: Class II
Product Code: FGE
Dated: May 23, 2025
Received: May 23, 2025

Dear 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 (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 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 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.

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 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 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.

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (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 systems (QS) regulation (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,

Kellie B. Kelm -S

for
Michael Hoffmann
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242845

Device Name

EGIS Biliary Double Bare Stent (BDB080405)

Indications for Use *(Describe)*

The EGIS Biliary Double 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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
K242845

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

Date the summary was prepared per (21 CFR 807.92(a)(a)): 10/3/2024

Submitted by:

Applicant:	S&G BIOTECH INC.
Applicant Address:	82, Bugok-ro, Pogok-eup, Cheoin-gu, Yongin-si, Gyeonggi-do, REPUBLIC OF KOREA (17023)
Contact Person:	Mr. Dave Kim Mtech Group LLC 7505 Fannin St. Suite 610, Houston, TX 77054
Contact Phone Number:	Tel: 713-467-2607
Contact e-mail	Email: davekim@mtechgroupllc.com

Device Information:

Trade Name:	EGIS Biliary Double Bare Stent
Common Name:	Biliary catheter and accessories
Regulation:	21 CFR 876.5010
Device Classification	II
Product Code:	FGE

Predicate Device:
K223354, EGIS Biliary Single Bare Stent

Device Description
EGIS Biliary Double Bare Stent has straight and round cylinder form made of nitinol wire. The double bare type is composed of two structures, an inner stent and an outer stent, and has a double-layer form. Each stent has the same structure as the single bare type of the product. A double layer is formed by overlapping a separately manufactured inner stent and an outer stent, and both ends are physically fixed using medical sutures. No additional bonding material in this process. This manufacturing method also allows the product to have more conformability and a smaller cell size.

Indication for Use:
The EGIS Biliary Double Bare Stent is indicated for the palliation of malignant strictures in the biliary tree.

Comparison to Predicates:
It has been demonstrated that the proposed device is substantially equivalent to the predicate device, the EGIS Biliary Single Bare Stent (K223354). Both devices have similar designs, same principle of operation and indications for use. There were some minor changes that polymer suture was added and structure was

changed to double layer. The substantial equivalence of the modifications were evaluated with performance testing.

Summary of Technological Characteristics (21 CFR 807.92(a)(6))

The following tests were performed to demonstrate that the proposed devices met the requirements. The EGIS Biliary Double Stent does not have a new intended use. It shows equivalent specifications with the predicate device in most of the parameters. There are no significant differences in these 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 Double Bare Sent and the predicate device (EGIS Biliary Single Bare Stent). The extrapolated force at 2000 gauss/cm supports safe usage of the device under such conditions.

Brief discussion of Nonclinical tests (21 CFR 807.92(b)(1))

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

- ISO 10993-3 – Genotoxicity (Ames test) & Genotoxicity (chromosomal aberration)
- ISO 10993-4- Hemolysis
- ISO 10993-5- Cytotoxicity
- ISO 10993-6- Implantation
- ISO 10993-10 - Sensitization & Intracutaneous Reactivity
- ISO 10993-11 – Acute systemic toxicity, subchronic toxicity, chronic systemic toxicity & pyrogenicity

Bench testing: Foreshortening, Stent integrity, Dimensional Verification, Radial Compression Force, Radial Outward Force, Pitting Corrosion, Corrosion, Crossing 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.

Clinical Test Conclusion
Clinical testing was not required for this submission.

Conclusion from nonclinical and clinical tests (21 CFR 807.92(b)(3))

The EGIS Biliary Double Bare Stent is substantially equivalent to the predicate device. Substantial equivalence was confirmed through non-clinical bench testing the biocompatibility evaluation.