March 13, 2026

Taewoong Medical Co., Ltd.
℅ Matthew Krueger
Principal Consultant
Biologics Consulting Group
100 Daingerfield Road, Suite 101
Alexandria, Virginia 22314

Re: K252648
Trade/Device Name: Niti-S SPAXUS Stent
Regulation Number: 21 CFR 876.5015
Regulation Name: Pancreatic Drainage Stent And Delivery System
Regulatory Class: Class II
Product Code: PCU, QXH
Dated: February 13, 2026
Received: February 13, 2026

Dear Matthew Krueger:

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), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 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)*
K252648

Device Name
Niti-S SPAXUS Stent

Indications for Use *(Describe)*

8mmx20mm stents:

The Niti-S SPAXUS™ Stent is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥6 cm in size, that are adherent to the gastric or bowel wall and are free of solid debris. The stent is intended for implantation up to 60 days and should be removed upon confirmation of pseudocyst resolution.

10mmx20mm and 16mmx20mm stents:

The Niti-S SPAXUS™ Stent is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥ 6 cm in size and walled-off necrosis ≥ 6 cm in size that are adherent to the gastric or bowel wall. Once placed, the Niti-S SPAXUS™ Stent functions as an access port allowing passage of standard and therapeutic endoscopes to facilitate debridement, irrigation and cystoscopy. The stent is intended for implantation up to 60 days and should be removed upon confirmation of pseudocyst or walled-off necrosis resolution. The Niti-S SPAXUS™ Stent is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of the gallbladder in patients with acute cholecystitis who are at high risk for surgery.

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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1. SUBMITTER INFORMATION

Applicant:	Taewoong Medical
Contact:	Yongjin Jeff Kim
Phone:	+82 70 4649 1543
Email:	jinjeff@stent.net
Address	14, Gojeong-ro, Wolgot-myeon, Gimpo-si, Gyeonggi-do, 10022, Republic of Korea

2. CORRESPONDENT INFORMATION

Contact:	Matthew Krueger
Title:	Principal Consultant
Firm:	Biologics Consulting Group

3. DATE PREPARED: FEBRUARY 13, 2026

4. DEVICE INFORMATION

Device Name:	Niti-S SPAXUS™ Stent
Common Name:	Pancreatic drainage stent and delivery system Gallbladder drainage stent and delivery system
Regulation Number:	21 CFR 876.5015 21 CFR 876.5016
Regulation Name:	Pancreatic drainage stent and delivery system
Product Code:	PCU, QXH
Regulatory Class:	Class II

5. PREDICATE DEVICE INFORMATION

Primary Predicate Device Name:	AXIOS Stent and Electrocautery-Enhanced Delivery System
510(k) Number:	K233318
Manufacturer:	Boston Scientific
Reference Device Name:	Esophageal TTS Stent
510(k) Number:	K240522
Manufacturer:	Taewoong Medical

Neither the predicate nor the reference devices have been subject to a design related recall.

6. DEVICE DESCRIPTION

The Niti-S SPAXUS™ Stent is a fully covered, self-expanding metallic stent. The stent is constructed from nickel-titanium alloy (nitinol), which provides flexibility, durability, and self-expansion properties. Its bi-flange design provides stable lumen apposition and helps mitigate migration risk. The complete silicone coating helps prevent leakage during drainage and facilitates the safe removal of the device. Radiopaque markers made of platinum/iridium and stainless steel enhance visibility under fluoroscopic guidance, aiding precise placement and monitoring.

The Stent Delivery System (SDS) is a disposable, non-electrocautery system for the delivery and deployment of the stent at the target position. It is similar in design to the SDS used for the Esophageal TTS Stent (K240522).

7. INDICATIONS FOR USE

8mm×20mm stents:

The Niti-S SPAXUS™ Stent is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥6 cm in size, that are adherent to the gastric or bowel wall and are free of solid debris. The stent is intended for implantation up to 60 days and should be removed upon confirmation of pseudocyst resolution.

10mm×20mm and 16mm×20mm stents:

The Niti-S SPAXUS™ Stent is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥ 6 cm in size and walled-off necrosis ≥ 6 cm in size that are adherent to the gastric or bowel wall. Once placed, the Niti-S SPAXUS™ Stent functions as an access port allowing passage of standard and therapeutic endoscopes to facilitate debridement, irrigation and cystoscopy. The stent is intended for implantation up to 60 days and should be removed upon confirmation of pseudocyst or walled-off necrosis resolution. The Niti-S SPAXUS™ Stent is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of the gallbladder in patients with acute cholecystitis who are at high risk for surgery.

8. COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Indications for Use for the subject Niti-S SPAXUS™ Stent are identical to a subset of those cleared for the predicate devices. The following tables compare some of the key technological characteristics between the subject and predicate devices.

Table 1: Pancreas Comparison – Niti-S SPAXUS Stent vs. AXIOS Stent 510(k) Predicates

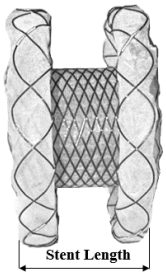
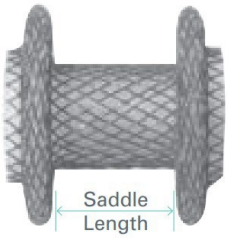
Feature	**Niti-S SPAXUS Stent**	**AXIOS Stent and Electrocautery-Enhanced Delivery System**
510(k) Number	K252648 (subject device)	K203132, K220112, K233318
Regulation	21 CFR 876.5015 (Pancreatic drainage stent and delivery system)	21 CFR 876.5015 (Pancreatic Drainage Stent and Delivery System)
Product Code(s)	PCU	PCU, KNS
Regulatory Class	Class II	Class II
Stent Sizes (Diameter × Length)	8mm × 20mm, 10mm × 20mm, 16mm × 20mm *(The listed length refers to the total stent length.)* 	6mm × 8mm 8mm × 8mm 10mm × 10mm 15mm × 10mm 15mm × 15mm 20mm × 10mm *(The listed length refers to the saddle length)* 
Primary Stent Materials	Nitinol with a silicone coating	Nitinol with a silicone coating
Delivery System Type	Standard delivery system (requires auxiliary tools, e.g., cystotome, for tissue penetration).	Available with both a standard delivery system and an electrocautery-enhanced delivery system.
Stent MRI Compatibility	MR Conditional	MR Conditional
Visualization	Radiopaque markers (Pt/Ir and 316L stainless steel) for fluoroscopic visibility.	Radiopaque markers (Pt/Ir) for fluoroscopic visibility.
Sterilization Method	Ethylene Oxide	Ethylene Oxide
Packaging	Provided sterile for single-patient use.	Provided sterile for single-patient use.

Table 2: Gallbladder Comparison – Niti-S SPAXUS Stent vs. AXIOS De Novo and 510(k) Predicates

Feature	Niti-S SPAXUS Stent	AXIOS Stent and Electrocautery-Enhanced Delivery System
510(k) Number	K252648 (subject device)	DEN230019, K233318
Regulation	21 CFR 876.5016 - Gallbladder drainage stent and delivery system	21 CFR 876.5016 - Gallbladder drainage stent and delivery system
Product Code	QXH	QXH
Regulatory Class	Class II	Class II
Stent Sizes (Diameter × Length)	10mm × 20mm and 16mm × 20mm *(The listed length refers to the total stent length.)*	10mm × 10mm 15mm × 10mm (*The listed length refers to the saddle length)*
Primary Stent Materials	Nitinol with a silicone coating	Nitinol with a silicone coating
Delivery System Type	Standard delivery system (requires auxiliary tools, e.g., cystotome, for tissue penetration).	Available with both a standard delivery system and an electrocautery-enhanced delivery system.
Stent MRI Compatibility	MR Conditional	MR Conditional
Visualization	Radiopaque markers (Pt/Ir and 316L stainless steel) for fluoroscopic visibility.	Radiopaque markers (Pt/Ir) for fluoroscopic visibility.
Sterilization Method	Ethylene Oxide	Ethylene Oxide
Packaging	Provided sterile for single-patient use.	Provided sterile for single-patient use.

9. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

Biocompatibility Testing

The stent materials of the subject devices are identical to those of the Niti-S Biliary Stent cleared in K240522 including its formulation, processing, and sterilization process, with no additional chemicals (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents) introduced.

Similarly, the SDS material of the subject device is identical to the Esophageal TTS Stent cleared in K240522 by Taewoong Medical, including its formulation, processing, and sterilization, with no additional chemicals added.

Therefore, additional biocompatibility testing for the Stent Delivery System is not required.

Electrical Safety

Not applicable. The subject device contains no electrical components, generates no electrical emissions, and uses no electrical energy of any type.

Electromagnetic Compatibility (EMC)

Not applicable. The subject device contains no electrical components, generates no electrical emissions, and uses no electrical energy of any type.

Software

Not applicable. The subject device contains no software.

Performance Testing

Additional performance testing was conducted to demonstrate that the device meets its design requirements and performs as intended. The performance tests include:

- Galvanic corrosion
- Corrosion
- Deployment Force
- Expansion force
- Compression force
- Dimensional
- Stent pull-out force
- Implant anchor function-retention
- Sterility verification
- Shelf life
- Package integrity

10. SUMMARY OF CLINICAL TESTING

A prospective, multi-center, single arm, non-inferiority, open label was conducted on 35 patients in South Korea using the Niti-S SPAXUS™ Stent. The purpose of the study was to evaluate safety and effectiveness of the Niti-S SPAXUS™ Stent in endoscopic ultrasound-guided transluminal drainage for the treatment of pancreatic pseudocysts ≥ 6 cm in size. Twenty-seven (27) males and 8 females comprised the 35 subjects enrolled in the study. The mean age was 53 ± 13 years (range, 22-77 years).

The primary safety endpoint was the incidence of serious adverse events (SAEs) related to the procedure or the Niti-S SPAXUS™ stent during the period of the study (i.e., from stent placement to 20 days ("Day 20") after the stent removal). The primary effectiveness endpoint was clinical success, defined as reduction in size of the pancreatic pseudocyst by at least 50% at 30 days (± 10 days; "Day 30") or 60 days (± 10 days; "Day 60") after the stent placement. One subject was excluded from the final effectiveness analysis. Secondary endpoints evaluated technical success, stent lumen patency, stent removal success, and procedure time.

There were no procedural or device-related SAEs reported during the study follow-up period. Clinical success was achieved in 33 of 34 subjects (97.1%) and non-inferiority was achieved.

Technical success was reported in 33 of 34 subjects (97.1%). Thirty-four (34) subjects (100%) maintained stent lumen patency at stent removal (Day 30 or 60 (± 10 days)). All stents were successfully removed (100%). The mean procedure time was 17.9 minutes ± 10.3 minutes.

In addition to this prospective study, three meta-analyses were referenced to help support the safe and effective use of the Niti-S SPAXUS™ Stent for the complete indications for use, including gallbladder drainage. These meta-analyses are described in:

- Suresh Kumar VC, Singh S, Moond V, Mohan BP, Aswath G, Khan HMA, Sapkota B, Adler DG. Safety and efficacy of lumen-apposing metal stents for endoscopic ultrasound-guided drainage of pancreatic fluid collections: a systematic review and meta-analysis. Endoscopy. 2025 Mar;57(3):282-290.
- Mangiavillano B, Lakhtakia S, Samanta J, Auriemma F, Vargas-Madrigal J, Arcidiacono PG, Barbera C, Ashhab H, Song TJ, Pham KD, Teoh AYB, Moon JH, Crinò SF, Kongkam P, Aragona G, De Lusong MA, Dhar J, Ofosu A, Ventra A, Paduano D, Franchellucci G, Repici A, Larghi A, Facciorusso A; PFC LAMS study group. Lumen-apposing metal stents for the treatment of pancreatic and peripancreatic fluid collections and bleeding risk: a propensity matched study. Endoscopy. 2024 Apr;56(4):249-257.
- Singh S, Suresh Kumar VC, Aswath G, Akbar Khan HM, Sapkota B, Vinayek R, Dutta S, Dahiya DS, Inamdar S, Mohan BP, Sharma N, Adler DG. Indirect comparison of various lumen-apposing metal stents for EUS-guided biliary and gallbladder drainage: a systematic review and meta-analysis. Gastrointest Endosc. 2024 Nov;100(5):829-839.e3.

11. BENEFIT-RISK ASSESSMENT

The benefit-risk assessment for the Niti-S SPAXUS™ Stent is based on nonclinical and clinical tests demonstrating substantial equivalence to the predicate AXIOS Stent (K233318).

Nonclinical tests, including galvanic corrosion, potentiodynamic polarization, deployment force, expansion/compression force, dimensional verification, stent pull-out force, implant anchor retention, torque strength, trackability, tensile strength, fatigue, and MR compatibility, confirmed that all acceptance criteria were met. These results show the device maintains structural integrity, resists corrosion, deploys reliably, and is MR Conditional up to 3T/2000 gauss/cm, with risks such as material degradation or migration mitigated through design and testing comparable to the predicate.

Clinical evidence from a prospective study (35 patients; 97.1% technical/clinical success, no device-related SAEs) and three meta-analyses supports the safety and effectiveness of the SPAXUS™ Stent. Singh et al. (2024) reported SPAXUS™ gallbladder drainage success rates of 95.9% technical/94.2% clinical, with 9.5% AEs vs. AXIOS 23.6%. Kumar et al. (2024) showed SPAXUS™ PFC drainage success of 98.2% technical/93.5% clinical, with 7.6% AEs vs. AXIOS 20.4%. Mangiavillano et al. (2024) propensity-matched study (132 patients/group) indicated SPAXUS™ bleeding (1.5%) and overall AEs (3.0%) lower than AXIOS (7.5% and 9.8%). The OUS marketing history (no recalls, low complaints) further affirms long-term safety.

Benefits include effective drainage of pancreatic pseudocysts/WON and gallbladder (high success rates) outweighing risks like bleeding (1.5-1.8%), migration (0.9-2.4%), or occlusion

(14.3%), which are lower or comparable to the predicate and are mitigated via labeling/instructions. The device is as safe and effective as the predicate.

12. CONCLUSION

The results of the performance testing described above demonstrate that the Niti-S SPAXUS™ Stent performs equivalently as compared to the predicate and reference devices and supports a determination of substantial equivalence.