April 5, 2023

Taewoong Medical Co., Ltd.
% Christy Foreman
Senior Consultant
Biologics Consulting Group Inc.
100 Daingerfield Rd., Suite 400
Alexandria, VA 22314

Re: K223256
Trade/Device Name: Optimos™ Cystotome
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: Class II
Product Code: KNS
Dated: March 7, 2023
Received: March 7, 2023

Dear Christy Foreman:

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 An -S

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)*
K223256

Device Name
Optimos™ Cystotome

Indications for Use *(Describe)*
The Optimos™ Cystotome is intended for use as an electrosurgical accessory to cannulate the transgastric or transduodenal wall and into a pancreatic pseudocyst that is visibly bulging into the gastrointestinal tract. This device is supplied sterile and is intended for single use only.

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.

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In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the Optimos™ Cystotome is provided below.

1. SUBMITTER

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Date Prepared: March 2, 2023

2. DEVICE

Device Trade Name:	Optimos™ Cystotome
Device Common Name:	Cystotome
Classification Name	876.4300, Endoscopic electrosurgical unit and accessories
Regulatory Class:	II
Product Code:	KNS

3. PREDICATE DEVICE AND REFERENCE DEVICES

Predicate Device: K022595, Wilson-Cook Cystotome

Reference Device: K150692, AXIOS Stent with Electrocautery Enhanced Delivery System

The AXIOS Stent is provided as a reference device for the sole electrode (electrode tip).

4. DEVICE DESCRIPTION

Optimos™ Cystotome is an electrode which uses heat generated from the application of high frequency (HF) energy through the monopolar electrode to puncture a hole in tissue. Following a fine-needle aspiration (FNA) procedure, it is positioned over a guidewire, so the applied part is located at the area of interest. The Optimos™ Cystotome is for use to drain pancreatic pseudocysts.

The Optimos™ Cystotome is a single use device provided sterile to the user. No reprocessing is performed by the user. The device is provided in three sizes, which have different diameters and tip lengths. The device itself consists of 3 parts: handle, sheath, and tip.

5. INTENDED USE/INDICATIONS FOR USE

The Optimos™ Cystotome is intended for use as an electrosurgical accessory to cannulate the transgastric or transduodenal wall and into a pancreatic pseudocyst that is visibly bulging into the gastrointestinal tract. This device is supplied sterile and is intended for single use only.

6. SUBSTANTIAL EQUIVALENCE

Comparison of Indications

The Wilson-Cook Cystotome is intended for use as an electrosurgical accessory to cannulate the transgastric or transduodenal wall and into a pancreatic pseudocyst that is visibly bulging into the gastrointestinal tract. This device is supplied sterile and is intended for single use only.

The indications for use statement of the subject device are identical to that of the predicate device.

Technological Comparisons

The table below compares the key technological feature of the subject devices to the predicate device, Wilson-Cook Cystotome (K022595).

Table 1: Technological Comparison

	Proposed Device	**Predicate Device**
510(k) Number	TDB	K022595
Applicant	Taewoong Medical	Wilson-Cook
Device Name	Optimos™ Cystotome	Cystotome
Classification Regulation	876.4300 Endoscopic electrosurgical unit and accessories	876.4300 Endoscopic electrosurgical unit and accessories
Product Code	KNS	KNS

	Proposed Device	**Predicate Device**
Indications for Use	The Optimos™ Cystotome is intended for use as an electrosurgical accessory to cannulate the transgastric or transduodenal wall and into a pancreatic pseudocyst that is visibly bulging into the gastrointestinal tract. This device is supplied sterile and is intended for single use only.	The Wilson-Cook Cystotome is intended for use as an electrosurgical accessory to cannulate the transgastric or transduodenal wall and into a pancreatic pseudocyst that is visibly bulging into the gastrointestinal tract. This device is supplied sterile and is intended for single use only.
Use	Endoscopic	Endoscopic
Number of Electrodes	1	2
Size of Electrodes	Needle Tip – Not Applicable Electrode Tip – 1.4 - 1.7 mm (Diameter) OCT1906: 1.4 mm OCT1907: 1.7 mm OCT1908: 1.7 mm	Needle tip – 0.097 mm Electrode Tip – 2.15 mm (Diameter) CST-10: 2.15 mm
Size of Sheath	Catheter attached to Needle - Not Applicable	Inner catheter attached to Needle Diameter X length: CST-10:1.7 mm(5Fr) X 1900 mm
	Catheter attached to Electrode tip (Diameter X Length): OCT1906: 2.0 mm X 1850mm OCT1907: 2.4 mm X 1850mm OCT1908: 2.8 mm X 1850mm	Outer catheter attached to Electrode tip Diameter X length: CST-10: 3.3mm (10Fr) X 1650 mm
Energy Delivered	1. Energy: Monopolar 2. Maximum rated input: 1kV peak-to-peak 3. Recommended generator settings: Pure cut mode, 80-120 Watts (400-500Vp)	1. Energy: Monopolar 2. Maximum rated input: 2kV peak-to-peak 3. Recommended generator settings: Pure cut mode, 80-120 Watts (400-500Vp)

	Proposed Device	Predicate Device
Compatible devices/equipment	0.025 ~ 0.035" Guide wire Endoscope with 3.2mm diameter or larger working channel	0.035" Guide wire Endoscope with 3.7mm diameter or larger working channel
Materials	Electrode: SUS 304 Sheath: PTFE	Unknown
Single Use	Yes	Yes
Sterile	EO Sterilization	EO Sterilization

7. PERFORMANCE DATA

Biocompatibility Testing

Table 2: Biocompatibility Characterization

Categorization	Optimos™ Cystotome	
Contact part	Direct contact to patient	Sheath (PTFE), Electrode Tip (STS 304)
	Indirect contact to patient	Saline port of Connector (PP), Sheath Tip (STS 304), Shaft wire (STS 304)
Categorization by ISO 10993-1	Nature of body contact	External communicating device Contact with Tissue
	Duration of contact	Limited exposure (A) – medical devices whose cumulative sum of single, multiple or repeated duration of contact is up to 24 h.
Sample preparation	Medical Device in Final Finished FormTable	

Table 3: Biocompatibility Test Results

Test Items	Result	P/F
Cytotoxicity	Reactivity grade - test sample: 0 - reagent control: 0 - negative control: 0 - positive control: 4	P

Test Items	Result	P/F
Intracutaneous reactivity	1. No abnormal signs 2. Normal body weight increase 3. Mean score was 0.00 in sterile saline extracts and 0.00 in cottonseed oil extracts	P
Sensitization (GPMT)	1. No abnormal signs 2. Normal body weight increase 3. The sensitization score was observed 0.0	P
Acute systemic toxicity	1. No abnormal signs 2. Normal body weight increase 3. No abnormal signs	P
Material mediated pyrogenicity test	1. No abnormal signs 2. Normal body weight increase 3. No animal showed body temperature increase of 0.5 ºC or above	P

Electrical safety and electromagnetic compatibility (EMC)

Table 4: Electrical Safety and Electromagnetic Compatibility Summary Results

Standard		Results
EN 60601-1 (2006) + A1:2013	General	P
IEC 60601-1:2005/AMD1:2012	Assessment of Basic Safety and Essential Performance of Medical Devices	P
IEC 60601-1-2	Collateral standard: Electromagnetic compatibility	P
IC 60601-2-2:2017	Particular standards: HF surgical equipment	P
IEC 60601-2-18	Particular equipment: endoscopic equipment	P

Bench Testing

Unit tests of the Optimos^{TM} Cystotome included a visual test, dimensional test, continuity test, endoscopic compatibility test, device operability test, high frequency dielectric strength test, detachable connector retention test, injection & leakage test, and tensile strength test. All tests passed the set acceptance criteria.

System tests to examine the thermal effects on tissue was conducted with fine needle aspiration, guidewire, endoscope, ESU as a system. The test results showed that all test samples meet the required performance, puncture tissues, and are compatible with all devices/equipment working together.

Thermal effects were evaluated on both the subject device and the equivalent device to validate the performance of the device. The performance of the Optimos™ Cystotome was comparable to the Wilson-Cook CST-10 Cystotome Cystoenterostomy Needle Knife at 18, 100, and 120W on porcine stomach tissue, and duodenum in the mucosa, submucosa, and muscularis propria. The test results met the acceptance criteria.

Table 5: Test Summary

Test sample	**Device name**	**Optimos™ Cystotome**		**Cystotome™ Cystoenterostomy Needle Knife**
	Manufacturer	**Taewoong Medical Co., Ltd**		**Wilson-Cook**
	Model number	**OCT1906**	**OCT1908**	**CST-10**
	Sample size	**18**	**18**	**18**
Acceptance criteria		1. The ability to puncture 2 type tissues (Porcine stomach and Duodenum) 2. Substantial equivalence of thermal damage: There should be no significant difference in measurement of size (length, width, and depth) of the thermal damage zone between subject device and predicate device.		
Generator power setting		Mono-polar Type, Auto Cut Mode (400 – 500Vp) Minimum: 80W, Default: 100W, Maximum: 120W		
Damage zone measurement		The thermal damage zone is measured under microscope and the depth is analyzed using histological strain, NADH ((nicotinamide adenine dinucleotide).		
Temperature-time history		Using Digital Thermometer, the temperature of the tissue surface was measured during the test. When the generator was activated, 69.7/60.6℃ and 2.5/66.2℃ were the highest temperature of stomach and duodenum tissue applied by the subject device/predicate device, respectively. The damage zone was measured after confirmation that the tissue samples were cool back to 37℃, baseline temperature.		

Animal Testing

Not applicable. Animal studies are not necessary to establish the substantial equivalence of this device.

Clinical Data

Not applicable. Clinical studies are not necessary to establish the substantial equivalence of this device.

8. CONCLUSION

Performance testing was conducted on all key performance attributes of the device. All samples met their acceptance criteria, demonstrating that when manufactured to specification, the device functions as intended and can be found substantially equivalent to the predicate device.