January 30, 2020

Wilson-Cook Medical, Inc.
Marge Walls-Walker
Sr. Regulatory Specialist
4900 Bethania Station Road
Winston-Salem, NC 27105

Re: K192339
Trade/Device Name: TeslaTome Bipolar Sphincterotome
Tesla Bipolar Active Cord
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical Unit and Accessories
Regulatory Class: Class II
Product Code: KNS
Dated: January 6, 2020
Received: January 10, 2020

Dear Marge Walls-Walker:

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,

Daniel G. Walter, Jr.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192339

Device Name
TeslaTome Bipolar Sphincterotome and Tesla Bipolar Active Cord

Indications for Use *(Describe)*
The TeslaTome Bipolar Sphincterotome is intended for cannulation of the ductal system and sphincterotomy. If preloaded, also aids in bridging difficult strictures during ERCP (endoscopic retrograde cholangiopancreatography). Also indicated for sphincterotome-aided, wire-guided selective cannulation of the biliary ducts.

The Tesla Bipolar Active Cord is used to connect the TeslaTome Bipolar Sphincterotome to compatible electrosurgical generators.

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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510(k) SUMMARY

Submitted By:

Marge Walls-Walker, Senior Regulatory Specialist

Wilson-Cook Medical, Inc./Cook Endoscopy

4900 Bethania Station Road

(336) 744-0157, x396290

January 6, 2020

Name of Device

Trade Names:	TeslaTome™ Bipolar Sphincterotome
	Tesla Bipolar Active Cord
Common/Usual Name:	Sphincterotome and Accessories
Proposed Classification Name(s):	Endoscopic Electrosurgical Unit and accessories,
	21CFR 876.4300, KNS, Class II

Predicate Devices

Olympus Single Use Preloaded Sphincterotome V (Clevercut); 510(k) No. k141991, cleared March 31. 2015.

Wilson-Cook Fusion OMNI Sphincterotome; 510(k) No. k172288, cleared April 17.2018

Reference Predicate device

Bitome Bipolar Sphincterotome; 510(k) No. k895842, cleared to market January 1.1990

Intended Use

The TeslaTome Bipolar Sphincterotome is intended for cannulation of the ductal system and sphincterotomy. If preloaded, also aids in bridging difficult strictures during ERCP (endoscopic retrograde cholangiopancreatography). Also indicated for sphincterotome-aided, wire-guided selective cannulation of the biliary ducts.

The Tesla Bipolar Active Cord is used to connect the TeslaTome Bipolar Sphincterotome to compatible electrosurgical generators.

Substantial Equivalence

The TeslaTome Bipolar Sphincterotome is substantially equivalent to the Olympus Single Use Preloaded Sphincterotome V (distal wire guided), k141991, cleared March 31, 2015 and the Fusion Omnitome, k172288, cleared April 17, 2018.

All three devices are endoscopic electrosurgical accessories composed of a single stainless steel drive wire within a triple-lumen polymer catheter. The proximal end of the catheter/wire assembly terminates in a handle, held by the physician or assistant during ERCP procedures and fulfills three (3) functions: connection to an electrosurgical generator, injection of diluted contrast, introduction of an endoscopic wire guide and manipulation of the cutting wire. The distal end contains a stainless steel cutting wire and ink and band markings. In the subject device and the Olympus distal wire guided sphincterotome, half of the cutting wire is insulated with a non-conductive polymer coating. All devices allow for short-wire, distal wire guide exchange through the separation of a weakened wall in the wire guide lumen that separates with manual control. The ability to separate the wire guide from the sphincterotome allows for the wire guide to be left in position in the ductal system once the sphincterotome is removed; additional therapeutic devices are then introduced without requiring additional cannulations. The subject device and predicate devices are also compatible with traditional long wire guides. The wire guide associated with the TeslaTome Bipolar line and referred to in this submission is the Acrobat Calibrated Wire Guide cleared to market via k142950 on 11.05.2014 and included in the Fusion Omni Sphincterotome submission as an accessory to the sphincterotome.

The TeslaTome Bipolar Sphincterotome seeks clearance for eight model numbers reflecting cutting wire length or 20 or 25 mm, and a .035”Acrobat II wire guide in either 260 cm or 450 cm length, and an optional rotatable handle. Cutting wire lengths and wire guide compatibility are the same as the Fusion OMNI predicate and similar to the Olympus sphincterotome. The distal ink markings and band placement are identical to the Fusion OMNI device and comparable to the Olympus device. All three devices are compatible with a range of endoscopes with the minimum channel size ranging from 4.2 mm (TeslaTome, OMNI) to 2.8 mm (Olympus).

Details on the exact re-order numbers and accessory compatibility are in **Table 1**.

Table 1: Reorder numbers for the subject device

RPN	Rotatable Handle	Cutting Wire length (mm)	Max Compatible Wire guide (WG) Diameter (in)	WG Length (cm)	WG Brand
TESLA-B2535-260	No	25	0.035	260	Acrobat 2
TESLA-B2035-260	No	20	0.035	260	Acrobat 2
TESLA-B2535-450	No	25	0.035	450	Acrobat 2
TESLA-B2035-450	No	20	0.035	450	Acrobat 2
TESLA-BR2535-260	Yes	25	0.035	260	Acrobat 2
TESLA-BR2035-260	Yes	20	0.035	260	Acrobat 2
TESLA-BR2535-450	Yes	25	0.035	450	Acrobat 2
TESLA-BR2035-450	Yes	20	0.035	450	Acrobat 2

The Tesla product family also includes the Tesla Bipolar Active Cord (TESLA-ACU-B) to facilitate connection to an Electrosurgical generator (ESU). As compared to the plug-fit active cords currently on the market for the predicate devices, the Tesla Bipolar Active Cords use a magnetic connection at the sphincterotome alignment but facilitate connection with ERBE generators on the distal end with conventional ESU-compatible plugs.

The minor differences in the Intended Uses reflect the scope of modern GI endoscopic practice in accessing and cannulating the biliary ductal system and do not impact the safety or the effectiveness of the subject device as labeled.

The primary distinction of the TeslaTome Bipolar Sphincterotomes from the named predicates is the electrosurgical current pathway. The Bipolar nomenclature indicates that the grounding of the current occurs close to the active electrode at the distal end of the sphincterotome by placement of an adjacent neutral electrode. **Figure 1** illustrates the difference in the current pathways. The lower figure illustrates the bipolar pathway of the subject device.

This bipolar current pathway was described in the reference predicate Bitome Bipolar Sphincterotome; 510(k) No. k895842, cleared to market January 1.1990 marketed by Everest Medical.

The bipolar current circuit is an established means of delivering energy well known in other endoscopic devices such as electric (hot) forceps and coagulation probes. The neutral electrode is the silver ink; the entire return pathway on the device from the ESU (endoscopic surgical unit) generator to the patient includes the silver ink, return wire and handle electrode. This silver ink neutral electrode is similarly placed to the coiled metal neutral electrode on the original Bitome.

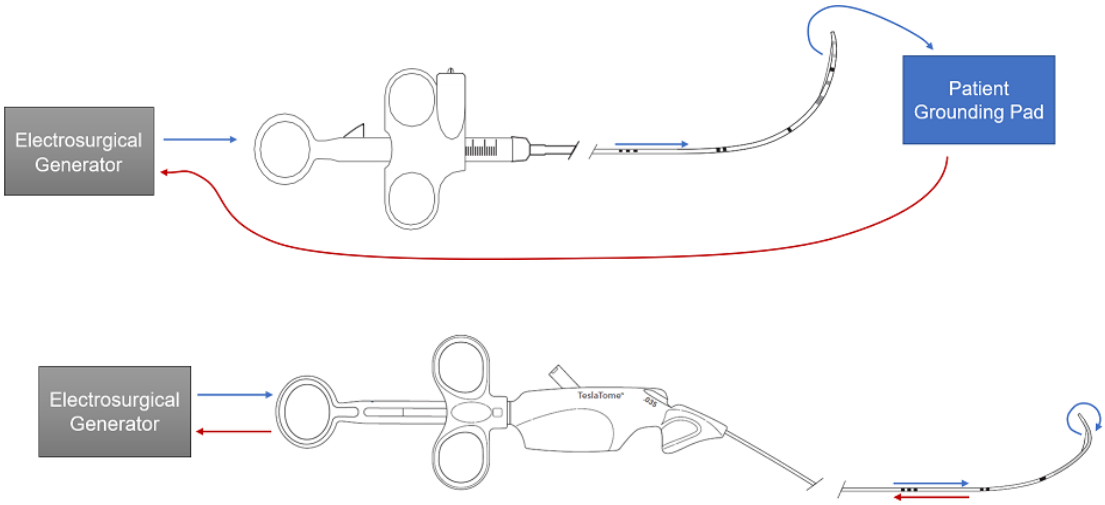

Figure 1: Monopolar (upper) and Bipolar (lower- subject device) circuits

The rotatable handle feature is a known technology in several lines of endoscopic accessories and allows controlled placement of the wire guide in the ductal system by rotation of the sphincterotome handle. The rotatable mechanism is separated from the electrical connection to prevent damage to current transfer components.

The Tesla Bipolar Active Cord is 223 cm long and in its current iteration compatible with ERBE generators. The Active cord is non-sterile and reusable. The cleaning instructions in the device IFU (Instructions for Use) have been validated with respect to the FDA guidance *"Reprocessing medical devices in healthcare settings: validation methods and labeling (June 2017)"* as well as relevant standards. Levels of hemoglobin and protein were found to be below the set acceptable level and all surface soiling was removed. The IFU also contains details on determining if the device has reached the end of its useful life. The Tesla Bipolar Active Cord is compatible only with the TeslaTome Bipolar Sphincterotome.

Discussion of Performance Tests and Test Results

Cook verification and clinically relevant simulated use testing established that design outputs met the design inputs and user needs for both the TeslaTome Bipolar Sphincterotome and the Tesla Bipolar Active Cord. These tests include verification at time zero or post six-month accelerated aging. Clinically relevant simulated use testing post six-month accelerated aging,

demonstrates that the sphincterotome and active cord meet the following design inputs/user needs:

User must be able to remove functional device from packaging and prepare for sphincterotomy.

User must be able to advance and remove sphincterotome through compatible endoscope and wire lock.

User must be able to perform contrast-based or wire-guided cannulation.

User must be able to perform sphincterotomy using an electrosurgical generator and Tesla Bipolar Active Cord.

User must be able to advance device into ductal system to perform selective cannulation of the hepatic system utilizing a wire guide.

User must be able to remove sphincterotome from a compatible endoscope while maintaining wire guide access to the ductal system.

Electrical testing for patients leads, handle and catheter temperature rise, single fault testing, leakage current, dielectric strength and contact impedance.

Finished product qualification to determine sterility, and EO residual levels.

Simulated distribution testing.

Testing specific to the bipolar transfer of electrosurgical energy establishes neutral electrode thermal performance by verifying that current is transferred to the neutral electrode to the cutting wire and no patient grounding pad is required for safe use. When used with the cut mode of an ERBE generator, the cutting wire produces functional results comparable to the predicate devices.

Additional tests specific to the Tesla Bipolar Active Cord include:

Connectivity to a TeslaTome Bipolar Sphincterotome and electrosurgical generator (ESU).

Delivery of current from ESU to a TeslaTome Bipolar Sphincterotome through the active cord.

Disconnection from ESU and the TeslaTome Bipolar Sphincterotome.

Electrical testing included patient leads, leakage current, dielectric strength, protection against excessive temperatures, excessive cord flexure or tension, mechanical strength and test finger.

The following biocompatibility tests: cytotoxicity, irritation, sensitization, acute systemic toxicity and material mediated pyrogenicity were conducted to establish the biological safety of the subject sphincterotome. As the subject active cord is unlikely to contact the patient and all

members of the endoscopy team wear conventional hand and eye protection, no biocompatibility testing was deemed necessary for the Tesla Bipolar Active Cord.

Conclusions Drawn from the Tests

Outcomes from the evaluation of the TeslaTome Bipolar Sphincterotome provide evidence of its ability to pass through the channel of a sphincterotome, cannulate and allow for contrast injection, accommodate either a short or long wire guide, facilitate distal (short wire) exchange and achieve sphincterotomy. Testing to verify performance of the Tesla Bipolar Active cord also provides evidence that the device will work as intended with the subject sphincterotome and an ERBE generator.

The subject and predicate devices are compliant with the relevant internationally recognized standards for electrosurgical medical equipment (ANSI/AAMI 60601-1) electrosurgical accessories (ANSI/AAMI 60601-2-2) and endoscopic equipment (ANSI/AAMI60601-2-18) and demonstrate substantial equivalence to the predicate devices in terms of intended use, biological safety and technological characteristics.