January 17, 2025

Wilson-Cook Medical Inc.
Lindsey Ebke
Regulatory Scientist
4900 Bethania Station Road
Winston Salem, North Carolina 27105

Re: K243568
Trade/Device Name: Teslatome Bipolar Sphincterotome; Tesla BiCord Active Cord
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: KNS
Dated: December 19, 2024
Received: December 19, 2024

Dear Lindsey Ebke:

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 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,

Anthony Lee -S

Anthony Lee, PhD, 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243568

Device Name

Teslatome Bipolar Sphincterotome;
Tesla BiCord Active Cord (TESLA-B-ACU)

Indications for Use *(Describe)*

This device is used for cannulation of the ductal system and for sphincterotomy. If preloaded, the device also aids in bridging difficult strictures during ERCP. Also indicated for sphincterotome-aided, wire-guided selective cannulation of the biliary ducts.

Tesla BiCord Active Cord:
This device 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.

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.

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510(k) #: K243568

510(k) Summary

Prepared on: 2025-01-07

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Wilson-Cook Medical Inc.
Applicant Address	4900 Bethania Station Road Winston Salem NC 27105 United States
Applicant Contact Telephone	567-236-0650
Applicant Contact	Dr. Lindsey Ebke
Applicant Contact Email	lindsey.ebke@cookmedical.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Teslatome Bipolar Sphincterotome; Tesla BiCord Active Cord (TESLA-B-ACU)
Common Name	Endoscopic electrosurgical unit and accessories
Classification Name	Unit, Electrosurgical, Endoscopic (With Or Without Accessories)
Regulation Number	876.4300
Product Code(s)	KNS

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K192339	TeslaTome Bipolar Sphincterotome, Tesla Bipolar Active Cord	KNS

Device Description Summary

21 CFR 807.92(a)(4)

In a sphincterotomy, access to the biliary tract is gained by passing a sphincterotome through a duodenoscope and positioning the distal tip adjacent to the major papilla. The papilla is cannulated using the tip of the sphincterotome. The papilla is then incised using an electrosurgical current applied to the cutting wire by an electrosurgical generator that is connected to the sphincterotome by an active cord.

The Teslatome consists of a three-ring handle, tri-lumen catheter, and cutting wire with a connection to an electrosurgical generator via the Tesla BiCord active cord. The connection delivers a current to the cutting wire that is exposed at the distal end of the device. A multi-lumen catheter allows for the injection of contrast and/or the passage over a prepositioned wire guide using the ports on the proximal end of the device.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

This device is used for cannulation of the ductal system and for sphincterotomy. If preloaded, the device also aids in bridging difficult strictures during ERCP. Also indicated for sphincterotome-aided, wire-guided selective cannulation of the biliary ducts.

Tesla BiCord Active Cord:
This device is used to connect the Teslatome Bipolar Sphincterotome to compatible electrosurgical generators.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The intended uses for the subject devices were updated to improve clarity and readability. The subject and predicate intended uses are functionally identical, and the change does not raise any new questions of safety or effectiveness.

Technological Comparison 21 CFR 807.92(a)(6)

The Teslatome Bipolar Sphincterotome and BiCord active cord have the same technological characteristics of the predicate devices K192339.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The non-clinical tests for seal strength, functional testing after simulated distribution, current carrying capacity, device burnout, neutral electrode thermal performance, and force of device pushability demonstrate adherence to the quality design and risk management systems of the manufacturer. The Teslatome Bipolar Sphincterotome and BiCord active cord are substantially equivalent to the currently cleared predicate devices.