September 29, 2025

Wilson-Cook Medical
Kaylin Davis
Regulatory Affairs Manager
4900 Bethania Station Road
Winston-Salem, North Carolina 27015

Re: K251104
Trade/Device Name: SureTome™ SW Sphincterotome with DomeTip
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical Unit and Accessories
Regulatory Class: Class II
Product Code: KNS
Dated: May 27, 2025
Received: August 27, 2025

Dear Kaylin Davis:

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 C. Lee, Ph.D., M.B.A.
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

# Indications for Use

| | |
|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | |
| Please provide the device trade name(s). | |
| SureTome™ SW Sphincterotome with DomeTip | |
| Please provide your Indications for Use below. | |
| This device is used for cannulation of the ductal system and for sphincterotomy. If preloaded, also aids in bridging difficult strictures during ERCP. | |
| Please select the types of uses (select one or both, as applicable). | ☒ Prescription Use (Part 21 CFR 801 Subpart D)<br>☐ Over-The-Counter Use (21 CFR 801 Subpart C) |

SureTome™ SW Sphincterotome with DomeTip ®
**21 CFR876.4300**
**Date Prepared: 23rd Sept 2025**

**Submitted By:**


| | |
|---|---|
| Submission: | Traditional 510(k) Premarket Notification |
| Applicant: | Wilson-Cook Medical |
| Applicant Address: | 4900 Bethania Station Road<br>Winston-Salem, NC 27015 |
| Contact: | Kaylin Davis |
| Email: | kaylin.davis@cookmedical.com |
| Contact Phone Number: | (336)744-0157 |


**Device Information:**

| | |
|---|---|
| Trade Name: | SureTome™ SW Sphincterotome with DomeTip ® |
| Device Common Name: | Endoscopic Electrosurgical Unit and Accessories |
| Classification Regulation: | 21 CFR876.4300 |
| Product Code: | KNS |
| Device Class: | Class II |
| Classification Panel: | Gastroenterology/Urology |

**Predicate Device:**

Primary Predicate: Fusion OMNI Sphincterotome (K172288, Wilson-Cook Medical) cleared to market April 17, 2018.

Reference Device: Tri-Tome pc Triple Lumen Sphincterotome (K172665, Wilson-Cook Medical) cleared to market May 24, 2018.

**Device Description:**

The SureTome™ SW Sphincterotome with DomeTip ® are sterile, single use devices compatible with the accessory channel of endoscope. The device consists of a long, thin plastic tube (cannula) with a wire running the length of its interior. A small portion of that wire is exposed at its distal end. The roof of the papilla is opened by passing high frequency current through the wire, exposing the biliary or pancreatic orifices for selective cannulation.

**Intended Use/Indications for Use:**

This device is used for cannulation of the ductal system and for sphincterotomy. If preloaded, also aids in bridging difficult strictures during ERCP.

**Technological Comparison**:

The subject device is substantially equivalent to the currently marketed predicate device, Fusion OMNI Sphincterotome (K172288, Wilson-Cook Medical) cleared to market April 17, 2018 and the reference device Tri-Tome pc Triple Lumen Sphincterotome (K172665, Wilson-Cook Medical) cleared to market May 24, 2018. In brief, the subject device is identical to the predicate device regarding the following:

- Intended use/indications of use
- Intended user
- Shelf life
- Sterility (Ethylene oxide, EO)
- For single use
- Principle of operation
- Patient contacting materials
- Outer Diameter
- Tip design
- Number of Lumens
- Distal Ink Markings
- Wire guide compatibility
- Length of cutting wire
- Type of cutting wire
- Preloaded wire guide option

The following technological differences exist between the modified devices and the currently marketed predicate device:

- Wire exchange technique (short wire only)
- Working length

- Breakthrough channel pre-slit
- Handle rotation
- Sphincterotome protector

**Performance Data:**

Non-clinical testing was performed to support substantial equivalence with the predicate device. Various bench tests were included in the performance data, including functional testing, rotation verification, orientation verification, electrosurgical accessory testing, wire guide compatibility, leakage testing, cutting wire joint strength, biocompatibility testing and sterilization testing.

**Conclusion**

The non-clinical data confirms that the SureTome™ Sphincterotome meets the design input requirements based on the intended use and supports the conclusion that this device does not raise new questions of safety and/or effectiveness and is substantially equivalent to the predicate device, Fusion OMNI Sphincterotome (K172288, Wilson-Cook Medical) and the reference device Tri-Tome pc Triple Lumen Sphincterotome (K172665, Wilson-Cook Medical).