June 02, 2026

Wilson-Cook Medical, Inc.
Alicia Altizer
Lead Regulatory Scientist
4900 Bethania Station Road
Winston-Salem, North Carolina 27105

Re: K253302
Trade/Device Name: Hemospray Endoscopic Hemostat
Regulation Number: 21 CFR 878.4456
Regulation Name: Hemostatic Device For Intraluminal Gastrointestinal Use
Regulatory Class: Class II
Product Code: QAU
Dated: September 29, 2025
Received: September 29, 2025

Dear Alicia Altizer:

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,

TEK N. LAMICHHANE -S

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Plastic and Reconstructive Surgery Devices
OHT4: Office of Surgical and Infection Control 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.

510(k) Number *(if known)*
K253302

Device Name
Hemospray® Endoscopic Hemostat

Indications for Use *(Describe)*
The Hemospray® Endoscopic Hemostat is used in adult patients for the hemostasis of nonvariceal gastrointestinal bleeding due to endoscopic procedures and medical conditions such as inflammatory lesions, GI vascular abnormalities, tumors, and ulcers.

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) Summary
(K253302)

I. Submitter Information

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Wilson-Cook Medical, Inc.
Contact:	Alicia M. Altizer, PhD
Applicant Address:	4900 Bethania Station Road
	Winston-Salem, NC 27105
Contact Phone Number:	765.463.7537
Date Prepared:	**June 01, 2026**

II. Device Information

Trade Name:	Hemospray® Endoscopic Hemostat
Common Name:	Hemospray
Classification Name:	Hemostatic device for intraluminal gastrointestinal use
Regulation Class:	Class II; Regulation Number 21 CFR 878.4456
Product Code:	QAU

III. Predicate Device

Hemospray® Endoscopic Hemostat (K200972), manufactured by Wilson-Cook Medical, Inc.

IV. Device Description

The Hemospray® Endoscopic Hemostat is an inert bentonite powder developed for endoscopic hemostasis. The powder is applied to the bleeding site using a carbon dioxide (CO_2)-powered delivery system with a catheter that is inserted and advanced through the working channel of an endoscope. Each device contains a minimum of 20 g powder. The device is sterilized by gamma irradiation and is meant for single use only. The powder is naturally eliminated from the body via the gastrointestinal tract.

V. Indications for Use

The Hemospray® Endoscopic Hemostat is used in adult patients for the hemostasis of nonvariceal gastrointestinal bleeding due to endoscopic procedures and medical conditions such as inflammatory lesions, GI vascular abnormalities, tumors, and ulcers.

VI. Substantial Equivalence Comparison

The purpose of this 510(k) is to revise the Instructions for Use to address mitigation measures related to scope adherence and unable to spray events. Table 1 provides a substantial equivalence comparison between the subject and predicate Hemospray devices.

Table 1. Substantial Equivalence Comparison

Parameter	Hemospray Endoscopic Hemostat (predicate device)	Hemospray Endoscopic Hemostat (subject device)
510(k) number	K200972	K253302
510(k) submitter or holder	Wilson-Cook Medical Inc.	Same as predicate device
Device classification	II	Same as predicate device
Classification name	Hemostatic Device For Endoscopic Gastrointestinal Use	Same as predicate device
Product code	QAU	Same as predicate device
Regulation number	21 CFR §878.4456	Same as predicate device
Intended Use	This device is used for hemostasis of nonvariceal gastrointestinal bleeding.	Same as predicate device
Indications for Use	The COOK Hemospray device is intended for hemostasis of non-variceal bleeds in the GI (gastrointestinal) tract. It is for prescription use only.	The Hemospray® Endoscopic Hemostat is used in adult patients for the hemostasis of nonvariceal gastrointestinal bleeding due to endoscopic procedures and medical conditions such as inflammatory lesions, GI vascular abnormalities, tumors, and ulcers.
Target population	Adult patients with non-variceal GI bleeding	Same as predicate device
Mode of action	Hemospray powder absorbs water from blood and the surrounding area to form a physical barrier to blood flow	Same as predicate device
Hemostatic agent	Bentonite powder (≥ 20 g)	Same as predicate device
Delivery system	Handle containing CO_2 cartridge and powder chamber, catheter	Same as predicate device
Catheter diameter	7 Fr or 10 Fr	Same as predicate device
Catheter length	220 cm	Same as predicate device

Parameter	Hemospray Endoscopic Hemostat (predicate device)	Hemospray Endoscopic Hemostat (subject device)
Endoscope accessory channel (EAC) compatibility	7 Fr = 2.8 mm EAC 10 Fr = 3.7 mm EAC	Same as predicate device
Maximum number of devices used/day/adult	3 devices	Same as predicate device
Single use or reusable	Single use	Same as predicate device
Sterility/Sterilization method	Gamma irradiation	Same as predicate device
Shelf life	3 years	Same as predicate device

VII. Performance Data

The technological characteristics (including materials, design, manufacturing processes, packaging, and sterilization) of the subject and predicate Hemospray devices are the same. The subject Hemospray device is identical to the predicate Hemospray device aside from the Instructions for Use. Bench and animal testing was performed to inform the changes to the Instructions for Use and ensure that the changes were safe and effective. Human factors (usability) testing was used to support that the applicable instructions are clear and able to be performed by the users.

IX. Conclusions

As summarized in Table 1, the technological characteristics (including materials, design, manufacturing processes, packaging, and sterilization) of the subject and predicate Hemospray devices are the same. The subject Hemospray device is identical to the predicate Hemospray device aside from the Instructions for Use. Nonclinical and usability testing support that the Instructions for Use changes are clear, effective, and able to be performed by the users. The subject Hemospray device remains substantially equivalent to the predicate Hemospray device.