June 10, 2020

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

Re: K200972
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: April 10, 2020
Received: April 13, 2020

Dear Ms. 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,

Cindy Chowdhury, Ph.D., M.B.A.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200972

Device Name
Hemospray Endoscopic Hemostat

Indications for Use *(Describe)*

The COOK Hemospray device is intended for hemostasis of non-variceal bleeds in the GI (gastrointestinal) tract. It is for prescription 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.

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510(k) Summary

In accordance with 21 CFR § 807.92, Wilson-Cook Medical, Inc submits the following 510(k) Summary.

Name: Wilson-Cook Medical, Inc. /Cook Endoscopy

Address: 4900 Bethania Station Road

Winston-Salem, North Carolina 27105

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Date: April 10, 2020

Trade Names: Hemospray® Endoscopic Hemostat

Common Name: Hemospray

Classification Name: Hemostasis Device for intraluminal gastrointestinal use

21 CFR 878.4456, QAU, Class II

Predicate Device: Hemospray Endoscopic Hemostat, DEN 170015

Intended Use: The COOK Hemospray device is intended for hemostasis of non-variceal bleeds in the GI (gastrointestinal) tract. It is for prescription use only.

Device Description:

Hemospray is an inert, bentonite powder developed for endoscopic hemostasis. The powder is delivered by use of a carbon dioxide powered delivery system and through a catheter inserted through the working channel of an endoscope which provides access to the site of the bleed. Each device contains approximately 20g of powder.

Substantial Equivalence:

A minor design change was made to the predicate Hemospray device to correct an observed failure mode of the introducer activation knob. It has been reported that the activation knob could separate or break during rotation to activate the CO_2 cartridge. This failure mode led to the initiation of a recall. The changes proposed in this submission creates a tensile strength design specification for the red activation knob component of the Hemospray Endoscopic Hemostat handle and add a new manufacturing inspection step that involves 100% proof loading every red activation knob to the established design specification prior to final device assembly. The following table compares the subject device to the predicate.

Table 1 : Predicate Device Comparison

Parameter	Hemospray Endoscopic Hemostat (subject device)	Hemospray Endoscopic Hemostat (DEN 170015)
Intended Use	This device is used for hemostasis of nonvariceal gastrointestinal bleeding.	Same
Supplied Sterile	Yes (Gamma)	Same
Disposable/Reusable	Disposable, Single Use	Same
Hemostatic agent	Bentonite powder ~ 20 g	Same
Delivery method	Powder propelled by CO2	Same
CO2 Pressure Regulator Setting	37 psi	Same
Catheter material	Polyethylene (PE)	Same
Catheter length	220 cm	Same
Catheter Diameter	7 FR or 10 FR	Same
Laser Markings	Yes, “Cook” on distal end of catheter	Same

Parameter	Hemospray Endoscopic Hemostat (subject device)	Hemospray Endoscopic Hemostat (DEN 170015)
Endoscope Accessory Channel (EAC) compatibility	7 FR=2.8 mm EAC 10 FR=3.7 mm EAC	Same
Handle material	Polycarbonate	Same
Target Population	Adult with non-variceal GI bleeding (NVGIB)	Same
Max number of devices used /day/adult	3 devices, ~ 60 gm of powder	Same

Device Modification:

A modification is being made to address the root cause associated with the voluntary recall (RES84822 (temp)) initiated by Cook on 1/16/2020; specifically, the modification is intended to address the potential for the activation knob component of the Hemospray introducer system to separate or break and potentially eject the CO_2 cartridge under pressure toward the physician or patient. The changes proposed in this submission creates a tensile strength design specification for the red activation knob component of the Hemospray Endoscopic Hemostat handle, thereby establishing pass/fail limits of the component and add a new manufacturing inspection step that involves 100% proof loading every red activation knob to the established design specification prior to final device assembly.

Bench testing demonstrated the subject device met the established performance requirement to fulfill the intended use. This testing provides reasonable assurance that the subject device will function as intended. The modification to the subject device does not raise new questions of safety or effectiveness as compared to the predicate device.

Summary of non-clinical evaluation:

A new tensile strength design specification for the red activation knob was developed based on a human factors study that evaluated the maximum force a user could apply to the red activation knob during use. The sample preparation for bench testing involved proof loading the red activation knobs to the established design specification followed by 2X gamma sterilization prior to tensile testing to failure. All

tested samples had tensile strength greater than the established design specification thereby confirming that the subject device performs as intended.

Conclusion:

The subject Hemospray device is substantially equivalent to the predicate Hemospray device subject of DEN 170015 with respect to intended use, key operating principles, materials of construction, and technological characteristics. The risks associated with the modification of the design by addition of a design requirement to the subject device have been adequately addressed through our Design Control Processes.