May 7, 2018

Wilson-Cook Medical, Inc./Cook Endoscopy
William D. Voorhees, Ph.D.
Vice President/Chief Science Officer
MED Institute, Inc.
4900 Bethania Station Road
Winston-Salem, NC 27105

Re: DEN170015
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: March 8, 2017
Received: March 9, 2017

Dear Dr. Voorhees:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Hemospray® Endoscopic Hemostat, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The COOK Hemospray® Endoscopic Hemostat is used for hemostasis of non-variceal gastrointestinal bleeding.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Hemospray® Endoscopic Hemostat, and substantially equivalent devices of this generic type, into Class II under the generic name hemostatic device for intraluminal gastrointestinal use.

FDA identifies this generic type of device as:

> **Hemostatic device for intraluminal gastrointestinal use**. A hemostatic device for intraluminal gastrointestinal use is a prescription device that is endoscopically applied to the upper and/or lower gastrointestinal tract and is intended to produce hemostasis via absorption of fluid or by other physical means.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of

the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register classifying the device type.

On March 9, 2017, FDA received your De Novo requesting classification of the Hemospray® Endoscopic Hemostat. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Hemospray® Endoscopic Hemostat into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the Hemospray® Endoscopic Hemostat can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk	**Mitigation Measures**
Bleeding - Inability to achieve hemostasis - Recurrence of bleeding	*In vivo* performance testing Non-clinical performance testing Labeling
Infection	Sterilization validation Shelf life testing Labeling
Adverse tissue reaction	*In vivo* performance testing Non-clinical performance testing Biocompatibility evaluation Labeling
Obstruction of gastrointestinal (GI) tract	*In vivo* performance testing Labeling
GI distension or perforation	*In vivo* performance testing Labeling
Vascular obstruction - Ischemia - Emboli formation	*In vivo* performance testing Non-clinical performance testing Labeling
Tissue trauma	*In vivo* performance testing Non-clinical performance testing Labeling
Improper device use	*In vivo* performance testing Labeling

In combination with the general controls of the FD&C Act, the hemostatic device for intraluminal gastrointestinal use is subject to the following special controls:

1. The device must be demonstrated to be biocompatible.

2. Performance data must support the sterility and pyrogenicity of the device.

3. Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.

4. *In vivo* performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The testing must evaluate the following:

    a) The ability to deliver the hemostatic material to the bleeding site;
    b) The ability to achieve hemostasis in a clinically relevant model of gastrointestinal bleeding; and
    c) Safety endpoints, including thromboembolic events, local and systemic toxicity, tissue trauma, gastrointestinal tract obstruction, and bowel distension and perforation.

5. Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be evaluated:

    a) Materials characterization of all components must demonstrate the device meets established specifications, which must include compositional identity and purity, characterization of impurities, physical characteristics, and reactivity with fluids.
    b) Performance testing must demonstrate the mechanical integrity and functionality of the system used to deliver the device and demonstrate the device meets established specifications, including output pressure for propellant-based systems.

6. Labeling must include:

    a) Information identifying and explaining how to use the device and its components; and
    b) A shelf life.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the hemostatic device for intraluminal gastrointestinal use they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Maegen Colehour, M.S. at 301-796-6436.

Sincerely,

Angela C. Krueger -S

Angela C. Krueger
Deputy Director, Engineering and Science Review
Office of Device Evaluation
Center for Devices and Radiological Health