DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 19, 2016

Cook Incorporated
David Lehr, RAC
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, Indiana 47404

Re: K153778
Trade/Device Name: Nester® and Tornado® Embolization Coils
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: May 11, 2016
Received: May 12, 2016

Dear David Lehr:

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. 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); 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 Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153778

Device Name
Nester® and Tornado® Embolization Coils

Indications for Use *(Describe)*
The Nester® and Tornado® Embolization Coils are intended for arterial and venous embolization in the peripheral vasculature.

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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2.0 510(k) SUMMARY

As required by 21 CFR §807.92
Date Prepared: April 1, 2016

I. SUBMITTER

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Contact:	David Lehr, RAC
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone Number:	(812) 335-3575 ext. 102309
Contact Fax Number:	(812) 332-0281

II. DEVICE

Trade Name:	Nester® and Tornado® Embolization Coils
Common Name:	Vascular Embolization Device
Classification Name:	Device, Vascular, For Promoting Embolization
Regulation/Class:	21 CFR §870.3300/Class II
Product Code	KRD

III. PREDICATE DEVICE

The device subject of this submission is considered substantially equivalent to the predicate device, the Cook Retracta® Detachable Embolization Coil (K123712/K151676). This predicate has never been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The Nester® and Tornado® Embolization Coils are constructed from coiled platinum wire and synthetic fibers. The wire forms primary coil diameters that can be delivered through catheters with end hole diameters of 0.018, 0.035, and 0.038 inch. For the Nester® Embolization Coils, the extended embolus lengths range from 3 to 20 cm, and upon deployment the coiled embolus diameters range from 2 to 20 mm. For the Tornado® Embolization Coils, the extended embolus lengths range from 2 to 14.2 cm, and upon deployment the coiled embolus tapering diameters range from 3/2 to 10/5 mm.

V. INDICATIONS FOR USE

The Nester® and Tornado® Embolization Coils are intended for arterial and venous embolization in the peripheral vasculature.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject devices, the Nester® and Tornado® Embolization Coils, and the predicate device, the Retracta® Detachable Embolization Coil (K123712/151676), are substantially equivalent in that these devices have identical intended uses and similar technological characteristics. The predicate device is a combined embolization coil and delivery wire. Its embolization coil (made of platinum wire and nylon fibers) is delivered by a detachment mechanism. The subject devices are pushable embolization coils (also made of platinum wire and nylon fibers) delivered with a wire guide through a delivery catheter. The predicate coils (intended for delivery through catheters with an end hole size of 0.035 inch) have a helical shape, and are available in lengths of 7 cm or 14 cm and diameters ranging from 4 to 20 mm. The subject Nester coils (intended for delivery through catheters with end hole sizes of 0.018, 0.035, and 0.038 inch) also have a helical shape and are available in lengths ranging from 2 to 20 cm and in diameters ranging from 2 to 20 mm. The subject Tornado coils (also intended for delivery through catheters with end hole sizes of 0.018, 0.035, and 0.038 inch) have a tapered vortex (or tornado) shape and are available in lengths ranging from 2.0 to 14.2 cm and tapering diameters ranging from 3/2 to 10/5 mm. Additionally, the subject devices, like the predicate device, are labeled as MR Conditional. However, there are differences in the MR scanning conditions to reflect the testing performed on the subject devices. Based on the comparison of the design, intended use, materials, fundamental technology, and principle of operation, the subject devices are considered to be substantially equivalent to the currently marketed predicate device.

VII. PERFORMANCE DATA

The subject devices underwent the applicable testing listed below to ensure reliable design and performance under the testing parameters. Performance (bench, MRI, and animal) and biocompatibility testing was conducted in accordance with applicable FDA guidance documents to confirm the reliable performance of critical device characteristics.

- Biocompatibility Testing – Cytotoxicity, Sensitization, Intracutaneous Reactivity, Acute Systemic Toxicity, Subchronic Toxicity, Genotoxicity, Implantation, Hemocompatibility, and Pyrogenicity tests were performed on the implantable embolization coils. Cytotoxicity, Sensitization, Intracutaneous Reactivity, Acute Systemic Toxicity, and Hemocompatibility tests were performed on the device's

loading stylet and loading cartridge. All tests results met the acceptance criteria, where applicable, or demonstrated that the device is biocompatible.

- Wire Tensile Testing – Testing shows the raw wire has a peak load value greater than or equal to the minimum tensile strength requirements. The predetermined acceptance criteria were met.
- Coil Tensile Testing – Testing characterized the embolization coils' uniaxial tensile strength.
- Rotations to Failure Testing – Testing characterized the embolization coils' torque strength.
- Delivery Friction Testing – Testing shows that the embolization coils fully deploy into the portion of the target artery in an anatomical model. The predetermined acceptance criteria were met.
- Delivery Fatigue Testing – Testing shows that the embolization coils do not have any visual defect after delivery. The predetermined acceptance criteria were met.
- Fiber Security Testing – Testing shows that an entire fiber is not released from the coils during simulated delivery conditions. The predetermined acceptance criteria were met.
- MRI Testing – MRI compatibility was assessed by evaluating magnetic field interactions (displacement force and torque), artifact, and RF-induced heating in accordance with FDA guidance titled, *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment*.
- Animal Testing – One-month, three-month, and six-month safety evaluations in swine were performed on platinum embolization coils. Testing shows that the target arteries do not indicate a substantially adverse biological response. The predetermined acceptance criteria were met.

VIII. CONCLUSIONS

The data included in this submission indicate that the subject devices do not raise new questions of safety or effectiveness compared to the predicate device. This supports a determination of substantial equivalence.