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

July 22, 2015

Cook Incorporated
David Lehr
Regulatory Affairs Specialist
750 Daniels Way, P.O. Box 489
Bloomington, Indiana 47402

Re: K151676
Trade/Device Name: Retracta Detachable Embolization Coil
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: June 19, 2015
Received: June 22, 2015

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)*
K151676

Device Name
Retracta® Detachable Embolization Coils

Indications for Use *(Describe)*
The Retracta Detachable Embolization Coil is 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K151676

510(k) SUMMARY

Submitted By: David Lehr, RAC
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Phone: (812) 335-3575 x102309
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Date Prepared: July 20, 2015

Device:

Submission:	Special 510(k) Premarket Notification
Trade Name:	Retracta® Detachable Embolization Coil
Common Name:	Vascular Embolization Device
Classification Name:	Device, Vascular, For Promoting Embolization
Regulation/Product Code:	21 CFR §870.3300/KRD
Class/Panel:	Class II/Cardiovascular

Indications for Use:

The Retracta Detachable Embolization Coil is intended for arterial and venous embolization in the peripheral vasculature.

Predicate Device:

The device subject of this submission is substantially equivalent to the predicate device, the Retracta® Detachable Embolization Coils, cleared under 510(k) number K123712.

Comparison to Predicate Device:

It has been demonstrated that the Retracta Detachable Embolization Coil is comparable to the predicate device. The proposed device is identical in terms of intended use, principles of operation, materials of construction, and basic technological characteristics to the predicate device. The safety and effectiveness of the modifications are supported by testing. The modifications consist of changes to the taper length, proximal coil length, and outer diameter of the distal section of the delivery wire.

Device Description:

The Retracta Detachable Embolization Coil is comprised of a fibered platinum embolization coil connected to a delivery wire. The delivery wire is composed of a tapered nitinol mandril soldered

to two segments of coiled Inconel wire. The device is packaged in a spiral holder with an attached loading cartridge.

Test Data:

A risk assessment was performed to assess the risks presented by the subject device. The following design control activities were then performed in order to demonstrate that the modification to the delivery wire of the Retracta Detachable Embolization Coils met applicable design and performance requirements and support a determination of substantial equivalence.

- Deployment Friction Testing – Testing showed that the delivery friction of the proposed design is not statistically greater than that of the current design. The acceptance criterion was met.
- Retraction Friction Testing – Testing showed that the retraction friction of the proposed design is not statistically greater than that of the current design. The acceptance criterion was met.
- Tensile Testing – Testing showed that the tensile strength of the proposed design of the delivery wire is statistically greater than that of the current design and statistically greater than the predefined criterion. The acceptance criterion was met.
- Torque Testing – Testing showed that the number of rotations to failure of the proposed delivery wire is statistically greater than that of the current design and that the number of rotations to failure of the proposed delivery wire is greater than 10. The acceptance criterion was met.
- Design Validation in a Swine Arterial Model – In testing, the proposed design achieved performance ratings of “adequate” or “good” for all performance parameters. The acceptance criterion was met.

In conclusion, the results of these tests support a determination of substantial equivalence to the predicate device.