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

December 18, 2015

Cook Incorporated
Nozomi Yagi
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, Indiana 47404

Re: K150964
Trade/Device Name: MReye Flipper Detachable Embolization Coil and Delivery System
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: October 19, 2015
Received: October 20, 2015

Dear Nozomi Yagi:

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)*
K150964

Device Name
MReye® Flipper® Detachable Embolization Coil and Delivery System

Indications for Use *(Describe)*
MReye Flipper Detachable 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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510(k) SUMMARY

K150964

As required by 21 CFR §807.92
Date Prepared: October 19, 2015

I. SUBMITTER

Applicant:	Cook Incorporated
Contact:	David Lehr, RAC
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone Number:	(812) 335-3575 x102309
Contact Fax Number:	(812) 332-0281

II. DEVICE

Trade Name:	**MReye® Flipper® Detachable Embolization Coil and Delivery System**
Common Name:	Embolization coil
Classification Name:	Vascular embolization device
Panel:	Cardiovascular
Regulation:	21 CFR §870.3300
Product Code	KRD

III. PREDICATE DEVICE

The device subject of this submission is believed to warrant a determination of substantial equivalence to the predicate device, the Flipper® Detachable Embolization Coil (K063619).

IV.DEVICE DESCRIPTION

The MReye® Flipper® Detachable Embolization Coil and Delivery System consists of a fibered detachable embolization coil and a delivery system. The MReye Flipper Detachable Embolization Coils are constructed from coiled Inconel (nickel chromium alloy) wire and synthetic fibers. The wire forms primary coil diameters from 0.035 inch. Upon exiting from the catheter, the embolization coil forms a secondary curl in vasculature, ranging from 3 to 8 mm.

V. INDICATIONS FOR USE

MReye Flipper Detachable Embolization Coils are used for arterial and venous embolization in the peripheral vasculature. The indication for use is identical to the predicate device.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The modification included in this submission does not include any new technological characteristics. The MReye® Flipper® Detachable Embolization Coil and Delivery System is comparable to the predicate device. Specifically, the MReye® Flipper® Detachable Embolization Coil and Delivery System is identical to the predicate device in terms of intended use, principle of operation, materials of construction, and basic technological characteristics.

VII. PERFORMANCE DATA

The following test was performed to determine the appropriate Magnetic Resonance Imaging information for the proposed device:

- MRI Testing – MRI testing verifies that the implant will be labeled as MR Conditional with the applicable parameters described in the Instructions for Use.

VIII. CONCLUSIONS

The result of the testing provides reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements of its intended use. The proposed device also does not raise new questions of safety or effectiveness as compared to the predicate device and thus is substantially equivalent to the predicate device.