K052834





NOV 23 2005

## 510(k) SUMMARY

**Submitted By:** Lisa Webb, MBA, RAC
Senior Regulatory Affairs Specialist
Cook Incorporated
750 Daniels Way
P.O. Box 489
Bloomington, IN 47402
(812) 339-2235 x 2643
4 October 2004

**Device:**
Trade Name: MReye® Embolization Coil

Proposed Classification Name: Arterial Embolization Device

**Predicate Devices:**

The MReye® Embolization Coil is similar in terms of intended use, materials of construction, and technological characteristics to the predicate Cook Embolization Coil.

**Device Description**

The MReye® Embolization Coil is supplied sterile and is intended for one time use. The embolization coil is pre-loaded in a shipping cannula. The coil is constructed of Inconel and has wire diameters of 0.025, 0.035, and 0.038 inches. It is available in curled and straight shapes. The emboli size range is 0 mm (straight) to 15 mm. The embolization coil includes synthetic fibers evenly placed down the length of the coil. The device is introduced to the target vessel using an angiographic catheter (sold separately) and deployment is achieved by a wire guide (sold separately) pushing the coil out of the catheter.

**Substantial Equivalence**

Cook currently markets the Cook Embolization Coil which is substantially equivalent to the MReye® Embolization Coil. The similar indications for use and technological characteristics of the MReye® Embolization Coil as compared to the predicate device support a determination of substantial equivalency.

## Test Data

The MReye® Embolization Coil was subjected to the following tests to ensure reliable design and performance under the specified testing parameters.

- Delivery Friction Testing
- Coil Connection Testing
- Coil Deformation Testing
- Wire Tensile Strength
- Fiber Pull Out Testing
- Magnetic Resonance (MR) Testing
- Biocompatibility Testing

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its intended use in peripheral arterial and venous vessel embolization procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 23 2005

Cook Incorporated
c/o Ms. Lisa Webb
Senior Regulatory Affairs Specialist
P.O. Box 489
Bloomington, IN 47402-0489

Re: K052834
MReye® Embolization Coil
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II (Two)
Product Code: KRD
Dated: October 5, 2005
Received: October 6, 2005

Dear Ms. Webb:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vuchanen

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K052834

Device Name: MReye® Embolization Coil

Indications for Use: Used for peripheral arterial and venous vessel embolization procedures.

Prescription Use XX AND/OR Over-the-Counter Use

(Per 21 CFR 801 Subpart D) (21 CRF 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Donna R. Vochtman

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)
Division of Cardiovascular Devices

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