

DEC 20 1999

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K992121

510(k) Premarket Notification
Embolization Coil System
COOK INCORPORATED

Safety and Effectiveness Information

Submitted By: Lisa Webb, RAC
Regulatory Affairs Coordinator
COOK INCORPORATED
925 South Curry Pike
P.O. Box 489
Bloomington, IN 47402
(812) 339-2235
June 21, 1999

Device: Trade Name: Detach 11® and Detach 18®
Proposed Classification Name: Arterial Embolization Device

Predicate Devices:

Detach 11®/18® is similar in terms of intended use, materials of construction and technological characteristics to the predicate devices reviewed, the Embolization Coil Positioner Set, Hilal Embolization Microcoils™, the Guglielmi Detachable Coil® and the Fibered Platinum Coil.

Device Description

This embolization coil system is supplied sterile and is intended for one time use. The device is comprised of an introducer system with a premounted detachable embolization coil. The embolization coil is deployed when the interlocking threads between the coil and the delivery wire are "unscrewed" by turning the delivery wire counterclockwise approximately 25 times.

The introducer system consists of a delivery wire and a delivery wire inserter. The delivery wire inserter consists of a plastic delivery wire holder with the delivery wire and a cannula inserter containing the coil. A Detach Locking Device is also needed to use the set. This part is sold separately because several coils can be delivered through one Detach Locking Device. These components are further described below.

- Coil: The coil is constructed of platinum and is available in the following shapes: curled, straight, Tornado™, J-Coil Shape and Multiple J-Coil Shape. The coil is also available in three degrees of softness: Detach 18® standard, Detach 18® soft, and Detach 11®.
- Delivery Wire: The delivery wire is comprised of four components: a handle, the delivery wire, a marker band and a detach tip. These are constructed of platinum and PTFE coated stainless steel. The delivery wires for Detach 11® and Detach 18® are available in a

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length of 200 cm. The diameter of the Detach 11® delivery wire is 0.011 inches. The diameter of the Detach 18® delivery wire is 0.018 inches.

- Delivery Wire Inserter: The delivery wire inserter is also comprised of four components. These include a stainless steel tip, a polycarbonate tip fitting, polyethylene tubing and a nylon fitting.
- Detach Locking Device: The Detach Locking Device is basically a pin vise which ensures that the delivery wire does not move forward during coil detachment. This device does not contact the skin or the blood.

Substantial Equivalence

Four devices are currently marketed in the U.S. which are believed to be substantially equivalent to Detach 11®/18®. These devices include an Embolization Coil Positioner Set (COOK INC), Hilal Embolization Microcoils™ (COOK INC), the Guglielmi Detachable Coil® (Target Therapeutics®) and a Fibered Platinum Coil (Target Therapeutics®). All devices are introduced via the percutaneous method of entry using a catheter or microcatheter introducer.

The Embolization Coil Positioner Set was reviewed as substantially equivalent under K942189 and is indicated for arterial and venous embolization. The device is constructed of stainless steel and synthetic fiber with a coil wire diameter of 0.018 to 0.038 inches. The coils are available in straight or curled shapes with an emboli size range of 2 to 20 mm. A push-button release mechanism is the method of deployment.

Hilal Embolization Microcoils™ were reviewed as substantially equivalent under K901337 and are indicated for the embolization of arteriovenous malformations and other vascular lesions of the brain, spinal cord and spine. The device is constructed of platinum coil and synthetic fiber with a coil wire diameter of 0.018 inches. The coils are available in straight and curled shapes with an emboli size range of 3 to 10 mm. Deployment is achieved by a wire guide which pushes the coil out of the catheter.

The Guglielmi Detachable Coil® was reviewed as substantially equivalent under K951256 and K960705 and is indicated for embolization of intracranial aneurysms, arteriovenous malformations, arteriovenous fistulae and arterial venous embolizations in the peripheral vasculature. The device is constructed of platinum with a coil wire diameter of 0.010 to 0.018 inches. The coils are available in a helical shape with an emboli size range of 2 to 20 mm. The coil is deployed by electrolytic detachment from the wire guide.

The Fibered Platinum Coil was reviewed as substantially equivalent under K955293 and is indicated for arterial and venous embolization in the peripheral vasculature. The device is

**510(k) Premarket Notification
Embolization Coil System
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constructed of platinum and synthetic fiber with a coil wire diameter of 0.010 to 0.035 inches. The coils are available in the following shapes: straight, C-shaped, helical and complex helical. The emboli size range is 2 to 30 mm. Deployment is achieved by a wire guide which pushes the coil out of the catheter.

The Detach 11®/18® will be indicated for arterial and venous embolization. This device will be constructed of platinum with a coil wire diameter of 0.011, 0.014 and 0.018 inches. The coils will be available in curled, straight, Tornado™, J-coil and multiple J-coil shapes. The emboli size range will be 2 to 12 mm. The coil is deployed when interlocking threads between the coil and the delivery wire are “unscrewed.”

The similar indications for use and technological characteristics of the Detach 11® and Detach 18® Embolization Coil Systems as compared to the predicate devices support a determination of substantial equivalency.

Test Data

Detach 11®/18® was subjected to the following tests to assure reliable design and performance under the specified testing parameters. These tests were comprised of:

- ◆ Tensile tests: Detach 18®
- ◆ Tensile tests: Detach 11®
- ◆ Tensile tests: Detachable Coils
- ◆ Performance Test in a Microferret™ Catheter Mounted in a Phantom

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 20 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Lisa Webb
Regulatory Affairs Coordinator
Cook Incorporated
925 South Cury Pike
P.O. Box 489
Bloomington, IN 47402

Re: K992121
Embolization Coil System
Regulatory Class: III (Three)
Product Code: KRD
Dated: September 23, 1999
Received: September 24, 1999

Dear Ms. Webb:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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.

Page 2 - Ms. Lisa Webb

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Celia M. Witten".

Celia M. Witten, Ph.D., M.D.
Acting Director

Division of Cardiovascular, Respiratory
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

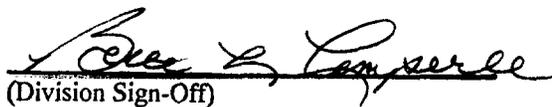
Enclosure

**Addendum to K992121
510(k) Premarket Notification
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510(k) Number (if known): K992121

Device Name: Embolization Coil System

Indications for Use: Arterial and venous embolization in the peripheral vasculature



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K992121

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____