JAN 11 2000

K993455

Safety and Effectiveness Information

Submitted By: Karen Bradburn
Regulatory Affairs Coordinator
COOK INCORPORATED
925 South Curry Pike
P.O. Box 489
Bloomington, IN 47402
(812) 339-2235

Device: Flipper™ Detachable Embolization Coil
Device, Embolization, Arterial (79KRD)
21 C.F.R. Part 870.3300

Predicate Devices

The Flipper™ Detachable Embolization Coil is similar in terms of intended use, materials of construction and technological characteristics to the predicate devices reviewed: Embolization Coil Positioner Set, Hilal Embolization Microcoils, Vascular Occlusion System, Guglielmi Detachable Coil and Fibered Platinum Coil.

Device Description

The Flipper™ Detachable Embolization Coil is used for arterial and venous embolization for the peripheral vasculature. This device is used in conjunction with the Flipper Detachable Coil Delivery Wire. The detachable coil delivery system provides safe delivery of embolization coils where the size of embolization coil is difficult to predetermine. A handle facilitates manipulation and provides safe and easy detachment of embolization coils. This device is provided sterile and is intended for one-time use.

The Flipper™ Detachable Embolization Coil consists of the embolization coils and the delivery wire. The embolization coils are manufactured using stainless steel wire with synthetic fibers. The delivery wire is manufactured using stainless steel with TFE coating. The device will be available in the following sizes and is compatible with catheters of 80 and 110 cm lengths.

Delivery Wire Diameter	0.035"
Extended Embolus Diameter	0.035"
Coil Length	3cm, 4cm, 5cm, 6cm, 8cm, 10cm, 12cm
Coil Embolus Diameter	3mm, 5mm, 6.5mm, 8mm

Substantial Equivalence

The Flipper™ Detachable Embolization Coil is similar to many devices already in commercial distribution for arterial and venous embolization. These devices include an Embolization Coil Positioner Set (Cook Incorporated), Hilal Embolization Microcoils (Cook Incorporated), the Vascular Occlusion System (Cordis Endovascular Systems 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 D.C. K940189 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 D.C. 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 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 Vascular Occlusion System was reviewed as substantially equivalent under D.C. K983483 and may be used to reduce or block the rate of blood flow in vessels of the peripheral and neurovasculature. It is intended for the interventional radiologic management of arteriovenous malformation, arteriovenous fistulas, and other vascular lesions of the brain, spinal cord and spine. The device is constructed of platinum and synthetic fiber with a coil wire diameter of 0.014 inches. The coils are available in straight, "C", flat spiral and complex shapes with an emboli size range of 2 to 10 mm. Deployment is achieved by a wire guide which pushes the coils out of the microcatheter.

The Guglielmi Detachable Coil was reviewed as substantially equivalent under D.C. K951256, K960705 and K962503 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 coils are deployed by electrolytic detachment from the wire guide.

The Fibered Platinum coil was reviewed as substantially equivalent under D.C. K955293 and is indicated for arterial and venous embolization in the peripheral vasculature. The device is 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 Flipper™ Detachable Embolization Coil will be indicated for arterial and venous embolization for the peripheral vasculature. The delivery wire will be constructed of stainless steel with a diameter of 0.035 inches. The stainless steel coils with synthetic fiber will be available in curled shapes with an coil embolus diameter range of 3 to 8 mm. The coil is deployed when interlocking threads between the coils and the delivery wire are unscrewed.

Performance Data

The following tests have been performed to evaluate the ability of the Flipper Detachable Embolization Coil to perform in accordance with the requirements of the design plan.

- *In-Vitro* Performance Test: Loading, Passage and Deployment
- Tensile Test: Coil Thread/Delivery System
- Tensile Test: Torque Wire to Braid Solder Joint

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 in the peripheral vasculature.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 11 2000

Ms. Karen Bradburn
Regulatory Affairs Coordinator
Cook, Inc.
P.O. Box 489
Bloomington, In 47402

Re: K993455
Flipper™ Detachable Embolization Coil
Regulatory Class: III
Product Code: KRD
Dated: October 12, 1999
Received: October 13, 1999

Dear Ms. Bradburn:

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 Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 continue 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.

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. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for

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

510(k) Number (if known): K 993455

Device Name: Flipper™ Detachable Embolization Coil

Indications for Use: Used for arterial and venous embolization in the peripheral vasculature.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K 993455

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-the-Counter Use_____

(Division Sign-Off)
Division of
and Neurological
510(k) Number