DEC 23 2008

510(k) Summary

Polyvinyl Alcohol Foam Embolization Particles
510(k) Summary
21 CFR 807.92
Date Prepared: 22 December 2008

1. Submitter Information:

Applicant:	Cook Incorporated
Address:	750 Daniels Way, P.O. Box 489 Bloomington, IN 47402
Phone Number:	1 (800) 468-1379
Fax Number:	(812) 332-0281
Contact:	Susanne Galin, RAC, Regulatory Affairs Specialist
Contact Address:	Cook Incorporated 750 Daniels Way P.O. Box 489 Bloomington, IN 47402
Contact Phone Number:	812-339-2235 x2296
Contact Fax Number:	812-332-0281

2. Device Information:

Trade name:	Polyvinyl Alcohol Foam Embolization Particles
Common name:	Polyvinyl Alcohol Foam Embolization Particles
Classification:	Class II
Regulation:	21 CFR §870.3300,
Product Code:	NAJ

3. Predicate Device:

Cook Incorporated's Polyvinyl Alcohol Foam Embolization Particles with their expanded indications for use statement are substantially equivalent (identical except for indication) to the Cook Incorporated's Polyvinyl Alcohol Foam Embolization Particles marketed prior to 1976.

Cook Incorporated's Polyvinyl Alcohol Foam Embolization Particles are also substantially equivalent in terms of materials and use to the Contour™ Emboli PVA cleared for market in K030966, Contour™ SE Microspheres cleared for market in K034068, and in terms of use to the Embosphere Microspheres, cleared for market in K021397.

4. Device Description:

Cook Incorporated Polyvinyl Alcohol Foam Embolization Particles are small, flexible, particles made of cross-linked polyvinyl alcohol. The particles are packaged dry and are provided sterile in sealed vials. They are intended for delivery to the target site by a catheter under fluoroscopic control.

Embolization particle sizes appropriate for use in symptomatic uterine fibroid treatment are 300-500 microns and 500-710 microns.

There have been no changes in the design, dimensions, or materials of the device.

5. Intended Use:

The Cook Polyvinyl Alcohol Foam Embolization Particles are intended for embolization of the blood supply to symptomatic uterine fibroids.

6. Technological Characteristics:

Cook Incorporated's Polyvinyl Alcohol Foam Embolization Particles described in this submission are physically identical to the predicate Cook Incorporated Polyvinyl Alcohol Foam Embolization Particles in terms of technological characteristics (design, dimensions and materials). They are also identical in terms of manufacturing process, sterilization, and packaging.

7. Clinical Data:

Clinical data was leveraged to support the substantial equivalence of this proposed device to predicate devices. Clinical data from Cook Incorporated's Polyvinyl Alcohol Foam Embolization Particles were obtained from published studies and from data generated by the FIBROID clinical registry.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 23 2008

Ms. Susanne Galin, RAC
Regulatory Affairs Specialist
COOK® Inc.
750 Daniels Way, P.O. Box 489
BLOOMINGTON IN 47402-0489

Re: K081768
Trade/Device Name: Polyvinyl Alcohol Foam Embolization Particles
Regulation Number: 21 CFR §870.3300
Regulation Name: Vascular embolization device
Regulatory Class: II
Product Codes: NAJ
Dated: December 12, 2008
Received: December 15, 2008

Dear Ms. Galin:

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 one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): K081768

Device Name: Polyvinyl Alcohol Foam Embolization Particles

Indications for Use:

The Cook Polyvinyl Alcohol Foam Embolization Particles are intended for embolization of the blood supply to symptomatic uterine fibroids.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K081768