K130259

MERIT MEDICAL

JUN 7 2013

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510(k) Summary

Bearing™ nsPVA Embolization Particles

General Provisions	Submitter Name:	Merit Medical Systems, Inc.
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	Telephone Number:	(781) 681-7963
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	Contact Person:	Linda Varroso
	Date of Preparation:	January 28, 2013
	Registration Number:	1721504
Subject Device	Trade Name:	Bearing™ nsPVA Embolization Particles
	Common/Usual Name:	PVA Embolization Particles
	Classification Name:	Vascular Embolization Device
Predicate Device	Trade Name:	Contour™ Embolization Particles
	Classification Name:	Vascular Embolization Device
	Premarket Notification:	K100663
	Manufacturer:	Boston Scientific Corporation
Classification	Class:	II
	21 CFR:	870.3300
	FDA Product Code:	KRD and NAJ
	Review Panel:	Cardiovascular, Obstetrics and Gynecology
Intended Use	Bearing™ nsPVA Embolization Particles are used for the embolization of peripheral hypervascularized tumors, including leiomyoma uteri and peripheral arteriovenous malformations (AVMs). Do not use particles smaller than 355 microns for the treatment of leiomyoma uteri.	

Device Description

Merit's Bearing™ nsPVA Embolization Particles are irregularly-shaped, biocompatible, hydrophilic, nonresorbable particles produced from polyvinyl alcohol. Bearing™ nsPVA Embolization Particles are contained in a sterile, 15 mL glass vial with a screw top-cap, packaged individually in a sterile peel pouch. Each vial contains 100 mg of Bearing™ nsPVA Embolization Particles, packaged dry. Each sterile vial is intended for single patient use. These embolization particles are intended to provide vascular occlusion or reduction of blood flow within target vessels upon selective placement through a variety of catheters.

Bearing™ nsPVA Embolization Particles are available in a variety of size ranges, depicted below.

Catalog Number	Size Range (µm)	Color Code	Minimum Compatible Catheter ID (inch)
V100EP	45-150	Yellow	0.020
V200EP	150-250	Purple	
V300EP	250-355	Dark Blue	
V400EP	355-500	Green	
V600EP	500-710	Orange	0.024
V800EP	710-1000	Light Blue	0.027
V1100EP	1000-1180	Red	0.040

The Bearing™ nsPVA Embolization Particles are particles of cross-linked polyvinyl alcohol (PVA). They are non-resorbable (permanent), hydrophilic and deformable particles that can be injected through a variety of catheters, depending on the size range, and are generally mixed with radiopaque contrast agent prior to their injection.

Comparison to Predicate	The technological characteristics of the subject device, Bearing™ nsPVA Embolization Particles, are substantially equivalent to the predicate device, Boston Scientific's Contour™ Embolization Particles. Based on the results of chemical analysis and testing, the subject and predicate devices are characterized as having the same chemical formula (polyvinyl alcohol). Both devices have the same chemical structure, residual process materials, and degree of cross-linking. The mechanical and physical properties are the same in that the injected particles allow embolization to the desired location in the body through a variety of catheters. The physician injects the particles to the targeted area under fluoroscopic visualization until the desired endpoint has been reached. The Embolization Particles occlude blood flow in a vessel lumen via mechanical means by obstructing the lumen of the vessel after injection. The occlusion can be the result of a single Embolization Particle obstructing the lumen or aggregation of multiple Embolization Particles creating a mechanical obstruction with thrombus filling the inter-particulate voids. The principle of operation for both devices is the same; they are designed to be used for the embolization of peripheral hypervascularized tumors, including leiomyoma uteri and peripheral arteriovenous malformations (AVMs). The subject and predicate device have the same fundamental design features including irregularly shaped dry particle size range characteristics, permanent implant duration of use, and color coded particle size labeling. There are minor differences between the subject and predicate device. The subject device's recommended catheter's minimum inner diameter (ID) sizes vary slightly from the predicate device. The selection of the ID sizes for the subject device allows more flexibility for the physician to target smaller arteries and deliver embolization particles as distally as possible to desired location. The predicate and subject device Instructions for Use are similar in that the physician is instructed to choose appropriate embolization particle sizes based on clinical presentation that best matches the desired level of occlusion for optimal clinical outcome. In addition, the subject and predicate device shelf life expectancy differs. These minor differences do not affect the safety and efficacy; therefore the subject device is substantially equivalent to the predicate device. Polyvinyl alcohol particles (PVA) have been used for more than thirty years in the field of embolization for the treatment of peripheral hypervascularized tumors, including leiomyoma uteri (uterine fibroids) and arteriovenous malformations (Specifically Boston Scientific's Contour™ Embolization Particles (K100663).

Safety & Performance Tests

Performance Standards and Guidance

No performance standards applicable to this device have been adopted under Section 514 of the Act. However, vascular embolization devices are subject to the special controls specified in "*Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices," December 29, 2004.*

Biocompatibility Standards

- **ISO 10993-1:2009,** Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- **ISO 10993-1:2010,** Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process Technical Corrigendum 1
- **ISO 10993-3:2003,** Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- **ISO 10993-4:2002,** Biological evaluation of medical devices - Part 4: Selection for tests for interactions with blood
- **ISO 10993-5:2009,** Biological evaluation of medical devices Part 5: Tests for *in vitro* cytotoxicity
- **ISO 10993-6:2007,** Biological evaluation of medical devices - Part 6: Test for local effects after implantation
- **ISO 10993-10:2010,** *Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization*
- **ISO 10993-11:2006,** Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- **NF EN ISO 10993-17:2009,** Biological evaluation of medical devices- Part 17: Establishment of allowable limits for leachable substances

Sterilization Standards

- **NF EN 556-1:2002,** *Sterilization of medical devices – Requirements for medical devices to be designated "STERILE" – Part 1: Requirements for terminally sterilized medical devices*
- **NF EN ISO 11137-1:2006,** *Medical Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

Safety & Performance Tests, Cont'd

Packaging and Aging Standards

- **ASTM F88:2009,** Standard Test Method for Seal Strength of Flexible Barrier Methods
- **ASTM F2096:2011,** Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
- **ASTM D4169-09:2009,** Standard Practice for Performance Testing of Shipping Containers and systems
- **ISO 2233:2000,** Packaging – Complete, filled transport packaging and unit loads – Conditioning for testing
- **BS EN ISO 11607:2010,** Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
- **ASTM F1140-07:2012,** Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages

The following is a list of all significant testing that was successfully completed:

Polyvinyl Alcohol (PVA) Particle Testing

- Chemical Analysis of the Final Sterilized Device
- Removal of Formaldehyde and/or other Processing Materials
- Particle Size Ranges (granulometry)
- Assessment of Particle Size Compatibility with Recommended Delivery Catheter(s)
- Evaluation of the Uniform Dispersion and Suspension of Particles within a Catheter (when mixed with the recommended contrast agents/interactive material(s) according to the labeled instructions.

Safety & Performance Tests, Cont'd

Packaging Performance – Packaging Qualification for 5-up Cartons for Merit Bearing™ nsPVA Sterile Pouches/Vials

- Primary Packaging Performance
- Visual Inspection Bubble Emission Testing
- Peel Strength Testing
- Sterile Barrier Maintenance After Exposure to Simulated Transportation and Storage Conditions

Accelerated Aging

- Product
  - Visual Inspection
  - Granulometric Analysis
  - Residual Formaldehyde
  - IR Analysis
- Primary Packaging
  - Visual Inspection
  - Seal width
  - Label Inspection
  - Burst Test
  - Seal Strength Test

Endotoxins:
Endotoxin testing is performed on each batch of Bearing™ nsPVA Embolization particles as they are labeled nonpyrogenic. The limit per device is 20 EU. Labeling indicates that the device is non pyrogenic. Each lot is tested for endotoxin prior to finished product release.

Sterility Assurance Level:
10^{-6}.

Clinical Data Review:
Clinical testing was not conducted on the Bearing nsPVA embolization particles due to the large amount of existing data on the use of PVA in embolotherapy for the last 30 years, and according to the evidence of equivalency between the Bearing nsPVA and the Contour Embolization Particles manufactured by Boston Scientific Corporation, and Cook PVA Particles manufactured by Cook Medical.
A literature based clinical data review was completed to analyze the available clinical data concerning polyvinyl alcohol (PVA) particles that are currently on the market. The search was conducted on medical/scientific databases, PubMed, and Cochrane Database of Systematic Reviews (CDSR). The literature review took into account the safety of the Embolization Particles. The data completed and collected by previously conducted clinical trials, applications of the product, and the absence of materovigilance reports concerning similar PVA embolic devices are sufficient to establish the efficacy and safety of the Merit Bearing™ nsPVA Embolization Particles.

Summary of Substantial Equivalence	Based on the same indications for use, design, scientific technology and results of safety and comparative bench testing, the subject device Bearing™ nsPVA Embolization Particles meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the Contour™ Embolization Particles, manufactured by Boston Scientific Corporation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 7, 2013

Merit Medical Systems, Inc.
% Ms. Linda Varroso
Director, Global Regulatory Affairs
1050 Hingham St
ROCKLAND MA 02370 US

Re: K130259
Trade/Device Name: Bearing™ nsPVA Embolization Particles
Regulation Number: 21 CFR 870.3330
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD, NAJ
Dated: May 13, 2013
Received: May 15, 2013

Dear Ms. Varroso:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, Misbranding by reference to premarket notification (21CFR 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.htmfor 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 Small Manufacturers, International and Consumer Assistance 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,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K130259

Device Name: Bearing™ nsPVA Embolization Particles

Indications for Use:

Bearing™ nsPVA Embolization Particles are used for the embolization of peripheral hypervascularized tumors, including leiomyoma uteri and peripheral arteriovenous malformations (AVMs).

Do not use particles smaller than 355 microns for the treatment of leiomyoma uteri.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
2013.06.07 15:16:35 -04'00'

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K130259