SECTION 5. 510(k) SUMMARY

K093973

(As Required By 21 CFR 807.92(a))

MAY 26 2010

Company Name: Codman & Shurtleff, Inc.

Company Address: 325 Paramount Drive
Raynham, MA 02767-0350

Phone: (508) 880-8097

Contact Person: Amarilys Machado
Manager, Regulatory Affairs

Submission Date: 12/23/09

Name of the Device: ORBIT GALAXY™ Detachable Coil System

Propriety / Trade Name: ORBIT GALAXY™ Detachable Coil System

Common Name: Artificial Embolization Device

Classification: Class II per 21 CFR 882.5950 (HCG)

Predicate Device:
The predicate device is listed in the table below:

Device	Company	510(k) Number / Concurrence Date	Product Code	Predicate for:
TRUFILL® DCS ORBIT™ Detachable Coil System	Codman & Shurtleff, Inc.	K080967 / 5-02-08	HCG	Intended Use Embolic Coil Delivery System Detachment Mechanism Manufacturing Sterilization

Device Description:

The ORBIT GALAXY™ Detachable Coil System consists of a delivery system (delivery tube and coil introducer) and a stretch resistant embolic coil. The delivery tube and coil introducer of the ORBIT GALAXY™ Detachable Coil System are identical to the delivery tube and coil introducer of the TRUFILL DCS ORBIT™ Detachable Coil System. The delivery tube is the body of the device and functions as a guidewire and a mini infusion catheter. The coil introducer is designed to protect the coil in the packaging dispenser and to provide support for introducing the coil into the infusion catheter. The coil is the implantable segment of the device. It is comprised of a platinum alloy wire and integrates a stretch resistant polymer monofilament through the inner diameter of the coil.

The TRUFILL® DCS Syringe II (sold separately) is required to properly purge and detach the coil. The coil is detached from the delivery tube by a proprietary hydraulic release mechanism.

The ORBIT GALAXY™ Detachable Coil System is packaged inside a protective dispenser tube. The product is held in place by means of a hub-to-dispenser tube clip. The entire system is packaged inside a sealed protective pouch. A luer valve is provided with the system if the user prefers to remove the syringe from the hub of the delivery tube after purging and prior to detaching the coil. The luer valve is attached to the packaging dispenser with a clip.

Intended Use:

1) The XTRASOFT™ ORBIT GALAXY™ Detachable Coil is indicated for embolizing intracranial aneurysms.

2) The Fill ORBIT GALAXY™ Detachable Coil and the Frame ORBIT GALAXY™ Detachable Coil are indicated for embolizing intracranial aneurysms and other vascular malformations such as arteriovenous malformations and arteriovenous fistulae of the neurovasculature.

   The Fill ORBIT GALAXY™ Detachable Coil and the Frame ORBIT GALAXY™ Detachable Coil are also intended for arterial and venous embolization in the peripheral vasculature.

Summary of Technological Characteristics of the Proposed to the Predicate Device:

The table below provides a comparative summary of the general characteristics of the proposed device to the predicate device.

Characteristics (Component and /or Material)	TRUFILL DCS ORBIT™ Detachable Coil (K080967)	ORBIT GALAXY™ Detachable Coil (K093973)
Intended Use	The TRUFILL DCS ORBIT™ Detachable Coil is indicated for embolizing intracranial aneurysms and other vascular malformations such as arteriovenous malformations and arteriovenous fistulae of the neurovasculature. The TRUFILL DCS ORBIT™ Detachable Coil is also intended for arterial and venous embolization in the peripheral vasculature.	1) The XTRASOFT™ ORBIT GALAXY™ Detachable Coil is indicated for embolizing intracranial aneurysms. 2) The Fill ORBIT GALAXY™ Detachable Coil and the Frame ORBIT GALAXY™ Detachable Coil are indicated for embolizing intracranial aneurysms and other vascular malformations such as arteriovenous malformations and arteriovenous fistulae of the neurovasculature. The Fill ORBIT GALAXY™ Detachable Coil and the Frame ORBIT GALAXY™ Detachable Coil are also intended for arterial and venous embolization in the peripheral vasculature.
Embolic Coil	Headpiece manufactured using Platinum/Tungsten; includes Gold/tin & Flux to Solder	No Change
	Nomenclature Fills, Standards	Nomenclature Fills, Frames, and Xtrasoft
	No stretch resistant suture	polypropylene stretch resistant suture
Coil Wire Diameter	0.0015 – 0.0040 inches	No Change
Primary Coil Diameter	0.010 – 0.016 inches	No Change
Softness Levels	Nomenclature Fills, Standards	Nomenclature Fills, Frames, and Xtrasoft
Secondary Coil Diameter	2 – 20 mm	2 – 26 mm
Secondary Shapes	Helical, Complex, and Mini Complex	No Change
Primary Coil Length	1.5 – 30.0 cm	No Change
Delivery System Useable Length	155 – 210 cm	No Change
Delivery System	0.014" and 0.018" guidewire compatible delivery system	No Change
	Hypotube welded to support coil with welded in-line marker bands	No Change
	Introducer: • Self splitting • Contains a zipper that also functions as a holder	No Change
Colorants	Blue Strain Relief	No Change
	Distal joint sleeve made of green Pebax 55D	No Change
Operating Principle	Hydraulic detachment mechanism	No Change
Shelf Life	2 years	No Change
Sterilization Process	100% Ethylene Oxide	No Change

Bench Test Summary:

In-vitro laboratory bench top testing was conducted to demonstrate the safety and effectiveness of the device, and to demonstrate that the device performs as it is intended. The following in-vitro bench top tests were conducted:

Test	Coils Tested	Results
Embolic Coil Length Verification	Xtrasoft and Frame	Met same specifications as predicate
Embolic Coil Diameter Verification	Xtrasoft, Fill, and Frame	Met same specifications as predicate
Embolic Coil Shape Visual Inspection	Xtrasoft, Fill, and Frame	Met same specifications as predicate
Headpiece Length Verification	Xtrasoft, Fill, and Frame	Met same specifications as predicate
Coil Softness	Xtrasoft, Frame, and Standard (control)	Met same specifications as predicate
Stretch Resistance Strength	Xtrasoft, Fill, and Frame	Met the acceptance criteria for the proposed device
Headpiece Attachment Strength	Xtrasoft, Fill, and Frame	Met same specifications as predicate
Atraumatic Bead Visual Inspection	Xtrasoft, Fill, and Frame	Met same specifications as predicate
Embolic Coil Placement Stability – In-vitro High Flow Vessel Model	Fill, Frame Xtrasoft	Met same specifications as predicate Xtrasoft coils are finishing coils indicated for embolizing intracranial aneurysms only.
Embolic Coil Attachment Strength	Xtrasoft, Fill, and Frame	Met same specifications as predicate
Embolic Coil Detachment Pressure	Xtrasoft, Fill, and Frame	Met same specifications as predicate
Luer Valve Burst Test	Luer Valve	Met same specifications as predicate

In-vivo and in-vitro Simulated Use Test Summary:

In-vivo and in-vitro testing was conducted to ensure that the user needs were adequately addressed. The performance of the coil was evaluated for aneurysm treatment in an in-vivo porcine model and in an in-vitro aneurysm model. The following attributes were tested in both the in-vivo porcine model and in the in-vitro aneurysm model.

Test	Coils Tested	Results
Embolic Coil Radiopacity	Xtrasoft	Met same specifications as predicate
Embolic Coil Protrusion	Xtrasoft, Fill, and Frame	Met same specifications as predicate
Coil Conformability	Xtrasoft, Fill, and Frame	Met same specifications as predicate
Coil Placement Stability	Xtrasoft, Fill, and Frame	Met same specifications as predicate
Packing of Embolic Coils	Xtrasoft, Fill, and Frame	Met same specifications as predicate
Retrievability of Embolic Coils	Xtrasoft, Fill, and Frame	Met same specifications as predicate
Deliverability through a Microcatheter	Xtrasoft, Fill, and Frame	Met same specifications as predicate
Pushability	Xtrasoft, Fill, and Frame	Met same specifications as predicate
Ability to Purge Product with Accessory Valve	Delivery tube and luer valve were tested	Met same specifications as predicate

Biocompatibility:

The ORBIT GALAXY Detachable Coil System met all the biocompatibility requirements as specified by the ISO 10993 Part 1, and the General Program Memorandum # G95-1 on Biological Evaluation of Medical Devices. The table below provides a summary of the biocompatibility test results and conclusions.

Orbit Galaxy Detachable Coil System Biocompatibility Summary[1]

Test	Results[2]	Conclusions[2]
In vitro Cytotoxicity Assay – ISO MEM Elution	No evidence of cytotoxicity	Non-cytotoxic
Sensitization – Guinea Pig Maximization	No evidence of irritation/sensitization	Non-sensitizing
ISO Intracutaneous Reactivity	No evidence of irritation	Non-irritant
ISO Acute Systemic Toxicity	No signs of toxicity.	Non-toxic
Materials Mediated Pyrogenicity	No increase in body temperature	Non-pyrogenic
In vitro Ames Bacterial Mutagenicity Assay	No significant increase in mutation frequencies	Non-mutagenic
In vitro Mouse Lymphoma Mutagenicity Assay	No significant increase in mutation frequencies	Non-mutagenic
In vitro Chromosome Aberration Assay	No significant increase in chromosome aberrations	Non-clastogenic / non-mutagenic
In vivo Mouse Bone Marrow Micronucleus Study	No significant increase in chromosome aberrations of bone marrow erythrocytes for Orbit SR Coils or Luer Valve	
ASTM Hemolysis – Direct Contact & Extract	Pass with a hemolytic score less than 2%	Non-hemolytic.
Partial Thromboplastin Time	Average clotting of Orbit SR Coils was 52% of the negative control. Average clotting time of Orbit Delivery System and Luer Valve was 100% of the negative control.	Orbit SR Coils passed as a mild activator of the intrinsic coagulation pathway. Orbit Delivery System and Luer Valve non-activator of the intrinsic coagulation pathway
Platelet & Leukocyte Count	Platelet & Leukocyte counts fell within 25% of the average reference material value.	Pass
Complement Activation C3a & SC5b-9 Assays	Activation was 0.8% (or less) of the normalized C3a and SC5b-9 concentrations produced by CVF.	Non-activator of complement activation pathways
180-day Rabbit Cerebral Cortex Implant Tissue Response Study	Comparable, very slight tissue reaction to Orbit SR Coils and control Orbit Coils without SR suture after 30 and 180-day implantation in cerebral cortex of rabbits. No implant testing conducted on delivery system or Luer Valve.	Orbit SR coils well tolerated in cerebral cortex of rabbits
Physiochemical Aqueous Extraction Test	Met the limits of the USP & EP Aqueous Extraction Tests.	Passed

[1]The Orbit Galaxy Detachable Coil System consists of a delivery system (delivery tube and coil introducer) and an implantable, stretch-resistant embolic coil (ORBIT SR Coil). A Luer Valve is provided with the system for users that prefer to remove the syringe from the hub of the delivery tube after purging and prior to detaching the coil. Separate biocompatibility testing was conducted for the delivery system, embolic coils, and Luer Valve.
[2]Results and conclusions are summarized for all three components (delivery system, embolic coils, and Luer Valve) unless otherwise noted.

Summary of Substantial Equivalence:

A comparison of the technological characteristics of the proposed device (ORBIT GALAXY™ Detachable Coil system) to the predicate device (TRUFILL DCS ORBIT™ Detachable Coil System) show the proposed device has the following same or similar technological characteristics to the device which received 510(k) clearance:

- Same intended use
- Same operating principle
- Similar materials
- Similar device dimensional specifications
- Similar manufacturing process
- Same shelf life and sterilization process

In summary, the ORBIT GALAXY™ Detachable Coil System is, in our opinion, substantially equivalent to the predicate device, TRUFILL® DCS ORBIT™ Detachable Coil.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MAY 2 6 2010

Codman & Shurtleff, Inc.
c/o Ms. Amarilys Machado
Manager, Regulatory Affairs
325 Paramount Drive
Raynham, MA 02767-0350

Re: K093973
Trade/Device Name: ORBIT GALAXY™ Detachable Coil System
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG, KRD
Dated: May 3, 2010
Received: May 6, 2010

Dear Ms. Machado:

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.htm for 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,

Kezia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093973

Device Name: ORBIT GALAXY™ Detachable Coil System
XTRASOFT™ ORBIT GALAXY™ Detachable Coil
Fill ORBIT GALAXY™ Detachable Coil
Frame ORBIT GALAXY™ Detachable Coil

Indications for Use:

1) The XTRASOFT™ ORBIT GALAXY™ Detachable Coil is indicated for embolizing intracranial aneurysms.

2) The Fill ORBIT GALAXY™ Detachable Coil and the Frame ORBIT GALAXY™ Detachable Coil are indicated for embolizing intracranial aneurysms and other vascular malformations such as arteriovenous malformations and arteriovenous fistulae of the neurovasculature.

   The Fill ORBIT GALAXY™ Detachable Coil and the Frame ORBIT GALAXY™ Detachable Coil are also intended for arterial and venous embolization in the peripheral vasculature.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

JEFFREY TOY

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K093973