510(k) Summary

(As Required By 21 CFR 807.92(a))

AUG 14 2012

A. Submitter Information

Submitter's name:	Codman & Shurtleff, Inc.
Address:	325 Paramount Drive Raynham, MA 02767
Telephone:	508.828.2840
Fax:	508.977.7979
Contact Person:	Joan Bartle
Date of Submission	June 15, 2012

B. Trade/Device Name:

Trade/Device Name:	AGILITY® Steerable Guidewire NEUROSCOUT® Steerable Guidewire
Common Name:	Guidewire
Classification Name:	Catheter, Guidewire
Regulation Number:	Class II per 21 CFR 870.1330

C. Predicate Devices:

Device	Company	510(k) Number	Product Code	Predicate For:
AGILITY Standard and Soft .010	Codman & Shurtleff, Inc.	K991646	DQX	Intended Use Design Materials Manufacturing Sterilization
AGILITY Standard and Soft .014	Codman & Shurtleff, Inc.	K001033	DQX	Intended Use Design Materials Manufacturing Sterilization
AGILITY Standard and Soft .016	Codman & Shurtleff, Inc.	K010511	DQX	Intended Use Design Materials Manufacturing Sterilization
NEUROSCOUT Standard and Soft .014	Codman & Shurtleff, Inc.	K100351	DQX	Intended Use Design Materials Manufacturing Sterilization

D. Device Description:

The hydrophilically coated **AGILITY® and NEUROSCOUT®** Steerable Guidewires consist of a stainless steel wire core and a radiopaque platinum/tungsten coil on the distal tip. The basic principle of the guidewires is to act as a monorail that catheters can track over to reach a particular area of the neuro and peripheral vasculature. They have a nominal outside diameter range of 0.012 to 0.016 inches and overall length of up to 350 cm. Guidewire length, diameter, and distal tip configuration are indicated on the product label. A steering/torquing device and a guidewire introducer are packaged with the guidewires.

E. Intended Use:

The AGILITY® Steerable Guidewires are intended for selective placement of microcatheters and other devices in the neuro and peripheral vasculature.

The NEUROSCOUT® Steerable Guidewires are intended for selective placement of microcatheters and other devices in the neuro and peripheral vasculature.

F. Summary of technological characteristics of the proposed to the predicate device:

The proposed AGILITY® Steerable Guidewires and NEUROSCOUT® Steerable Guidewires are the same as the currently cleared AGILITY® Steerable Guidewires and NEUROSCOUT® Steerable Guidewires with regard to intended use, function, design, manufacturing and sterilization processes. The proposed device modifications include material changes and the related manufacturing process changes. No new technological characteristics are being introduced with the proposed device.

A summary table including specifications of the proposed device compared with those of the predicate devices follows.

Comparative Information

Characteristics	AGILITY 10, 14, 16	NEUROSCOUT 14	Proposed Device
Classification	Class II	Class II	Class II
Intended Use	Selective placement of microcatheters and other devices in the neuro and peripheral vasculature	Selective placement of microcatheters and other devices in the neuro and peripheral vasculature	Selective placement of microcatheters and other devices in the neuro and peripheral vasculature
Operating Principle	The basic principle of the guidewires is to act as a monorail that catheters can track over to reach a particular area of the neuro and peripheral vasculature.	The basic principle of the guidewires is to act as a monorail that catheters can track over to reach a particular area of the neuro and peripheral vasculature.	The basic principle of the guidewires is to act as a monorail that catheters can track over to reach a particular area of the neuro and peripheral vasculature.
Shelf Life	2 years	2 years	2 years
Sterilization	EtO	EtO	EtO
Guidewire Length (cm)	100 – 350	100-300	Same as current
Guidewire Proximal Shaft Maximum Diameter (inches)	0.0110 – 0.0164	0.0144	Same as current
Guidewire Distal Coil Maximum Outer Diameter (inches)	0.0105 – 0.0155	0.0135	Same as current
Corewire Nominal Diameter (inches)	0.009 – 0.015	0.0133	Same as current
Corewire Material	Stainless Steel	Stainless Steel	Stainless Steel
Corewire Coating	Hydrophilic	Hydrophilic	Hydrophilic
Tip Style	Straight	Straight	Straight
Tip Shape	Flattened core	Flattened core	Flattened core
Shapeable Tip Length (cm)	2 – 5	2	Same as current
Tip Coil Length (Distal Length (cm)	5 – 45	10	Same as current
Coil wire size (inches)	0.0015 – 0.0025	0.002	Same as current
Coil material	Pt/W	Pt/W	Pt/W

Distal Tip Coating	Hydrophilic	Hydrophilic	Hydrophilic
Radiopaque Length (cm)	5 – 45	10	Same as current
Number of Joints	3	3	3
Joint Type (proximal to distal)	UV x 3	UV x 3	UV x 3

G. Testing Summary:

Design Verification testing was conducted according to *FDA Guidance for Coronary and Cerebrovascular Guidewires, 1995 and* ISO 11070:1998 *Sterile Single-Use Intravascular Catheter Introducers.* Bench testing data demonstrated that the AGILITY® Steerable Guidewires and NEUROSCOUT® Steerable Guidewires performed according to their description, intended use and the established performance characteristics. The testing, in conjunction with the similarities to the predicate devices, demonstrates the safety and effectiveness of the modified device for its intended use and determination of substantial equivalence. Clinical testing was not required to establish substantial equivalence.

The following tests were conducted to verify the modified design:

- Visual Inspection
- Dimensional Inspection
- Linear Tip Stiffness
- Torque Response
- Tensile Strength (Distal Tip)
- Tensile Strength (Middle Joint)
- Tensile Strength (Proximal Joint)
- Coating Adherence/Integrity (Particulates)
- Lubricity Testing
- Torque Strength (Rotations to Failure)

Full biocompatibility testing in accordance with ISO 10993-1 was conducted. Results demonstrated that the proposed devices meet all the same biocompatibility requirements as the predicate devices as specified by ISO 10993

Part 1 and the General Program Memorandum #G95-1 on Biological Evaluation of Medical Devices.

- *In Vitro* Cytotoxicity – MEM Elution
- Sensitization – Guinea Pig Maximization
- Intracutaneous/Irritation Reactivity
- Acute Systemic Toxicity
- Material Mediated Rabbit Pyrogenicity
- *In Vitro* Bacterial Mutagenicity – Ames Assay
- *In Vitro* Mouse Lymphoma Mutagenicity Assay
- *In Vivo* Mouse Bone Marrow Micronucleus Assay
- *In Vitro* Hemolysis (Direct Contact and Extract)
- Complement Activation (C3a Assay)
- Complement Activation (SC5b-9 Assay)
- Partial Thromboplastin Time (PTT)
- *In Vivo* Dog Thrombogenicity
- USP Physicochemical Tests (Aqueous)
- Physicochemical Tests (Non-Aqueous)

The packaging and sterilization for the proposed devices is identical to the packaging and sterilization for the current devices.

Based upon the design, materials, function and intended use comparison with currently marketed devices, and the non-clinical testing performed by Codman & Shurtleff, Inc., it is concluded that the AGILITY® Steerable Guidewires and NEUROSCOUT® Steerable Guidewires are substantially equivalent to the predicate AGILITY® Steerable Guidewires and NEUROSCOUT® Steerable Guidewires.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Codman & Shurtleff, Inc.
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Raynham, MA 02767-0350 US

AUG 14 2012

Re: K121776
Trade/Device Name: Agility steerable guidewire and NeuroScout steerable guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Guidewire
Regulatory Class: Class II
Product Code: DQX
Dated: June 15, 2012
Received: June 18, 2012

Dear Ms. Bartle:

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,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number (if known): K121776

Device Name:

AGILITY® Steerable Guidewire
NEUROSCOUT® Steerable Guidewire

Indications for Use:

The AGILITY® Steerable Guidewires are intended for selective placement of microcatheters and other devices in the neuro and peripheral vasculature.

The NEUROSCOUT® Steerable Guidewires are intended for selective placement of microcatheters and other devices in the neuro and peripheral vasculature.

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

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121776