K133625

FEB 24 2014

510(k) Summary

[As Required By 21 CFR 807.92(a)]

A. Sponsor

Submitter's Name: Codman & Shurtleff, Inc.
Address: 325 Paramount Drive
Raynham, MA 02767

Primary Contact: Hannah Foley
Telephone: (305) 265-6810
Fax: (305) 265-6889

Secondary Contact: Amarilys Machado
Telephone: (305) 265-6869
Fax: (305) 265-6889

B. Date Prepared: November 25, 2013

C. Device Name and Classification:

Proprietary Name: **AGILITY® Steerable Guidewire and NEUROSCOUT® Steerable Guidewire**

Common/Usual Name: Wire, Guide, Catheter

Classification Name: Neurovascular Catheter Guide Wire (21 CFR 870.1330), Class II

Product Code: MOF, DQX

D. Predicate Devices

This 510(k) submission provides pre-market notification of the AGILITY® and NEUROSCOUT® Steerable Guidewires' packaging change. The proposed packaging changes have not altered the fundamental technology of the predicate devices or the devices' intended use.

Table 1: Prior 510(k) Clearances

510(k) Number	Date Cleared	Name	Manufacturer
Predicate K121776	08/14/2012	AGILITY® Steerable Guidewires and NEUROSCOUT® Steerable Guidewires	Codman & Shurtleff, Inc.

E. Device Description

The hydrophilically coated AGILITY® and NEUROSCOUT® Steerable Guidewires consists of a stainless steel wire core and a radiopaque platinum/tungsten coil on the distal tip. 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 AGILITY® and NEUROSCOUT® Guidewires.

F. Indications for Use

The Codman AGILITY® and NEUROSCOUT® Guidewires are intended for selective placement of microcatheters and other devices within the neuro and peripheral vasculature.

G. Summary of Technological Characteristics of the Proposed Device to the Predicate Device

The proposed AGILITY and NEUROSCOUT Steerable Guidewires are identical to the predicate AGILITY and NEUROSCOUT Steerable Guidewires with regard to intended use, design, material, function, mechanism of action, clinical utility, manufacturing and sterilization process.

The AGILITY® and NEUROSCOUT® Steerable Guidewires were shown to be substantially equivalent to the predicate devices through comparison of indications for use, function, operating principle, bench testing, biocompatibility, and materials. A summary table including characteristics of the proposed device compared with those of the predicate device is provided in **Table 2.**

Table 2: Predicate Comparison Profile

Description	Predicate Device: AGILITY® & NEUROSCOUT® Steerable Guidewires (K121776)	This Submission: Device w/ Proposed Packaging Change: AGILITY® Steerable Guidewire	This Submission: Device w/ Proposed Packaging Change: NEUROSCOUT® Steerable Guidewire
Intended Use	The Codman AGILITY® and NEUROSCOUT® Guidewires are intended for selective placement of microcatheters and other devices within the neuro and peripheral vasculature.	Same	Same
Product Code	DQX	Same	Same
Classification	21 CFR 870.1330, Class II	Same	Same
Guidewire Length (cm)	**AGILITY®:** 175cm, 195cm, 205cm, & 350cm **NEUROSCOUT®:**	Same	Same

Table 2: Predicate Comparison Profile			
Description	**Predicate Device: AGILITY® & NEUROSCOUT® Steerable Guidewires (K121776)**	**This Submission: Device w/ Proposed Packaging Change: AGILITY® Steerable Guidewire**	**This Submission: Device w/ Proposed Packaging Change: NEUROSCOUT® Steerable Guidewire**
	205cm & 300cm		
Guidewire Proximal Shaft Maximum Diameter (Inches)	**AGILITY®:** 0.0110"(10), 0.0144"(14), & 0.0164" (16) **NEUROSCOUT®:** 0.0144" (14)	Same	Same
Shapeable Tip Length (cm)	2cm-5cm	Same	Same
Radiopaque Length (cm)	**AGILITY®:** 5cm-45cm **NEUROSCOUT®:** 10cm	Same	Same
Corewire Material	Stainless Steel	Same	Same
Coil Material	Platinum/ Tungsten	Same	Same
Corewire & Distal Tip Coating	Hydrophilic	Same	Same
Tip Style	Straight	Same	Same
Sterilization Method	Ethylene Oxide	Same	Same
Product Shelf-Life	Two (2) years	Same	Same

There are no new technological characteristic being introduced with the proposed packaging changes to the AGILITY® and NEUROSCOUT® Guidewires. The only differences are the packaging modifications identified for both products, which are summarized in **Table 3.**

Table 3: AGILITY® and NEUROSCOUT® Steerable Guidewires Packaging Modifications		
Description	**Proposed AGILITY® Steerable Guidewire**	**Proposed NEUROSCOUT® Steerable Guidewire**
Sterile Pouch Dimensions	X	X
Sterile Pouch Material: (Uncoated Tyvek 1073B)	X	X
Sterile Pouch Material: (Nylon/Polyethylene Film)	X	No Change
Sterile Pouch Vendor	X	No Change
Carton Dimensions	X	X
Carton Vendor	X	X
Hoop Dispenser Configuration	X*	No Change
*Applies only to the Large AGILITY 350cm Length Hoop Dispenser X=a change when compared to the predicate device		

H. Summary of Nonclinical testing:

The AGILITY® and NEUROSCOUT® Steerable Guidewires were evaluated and have been found to be substantially equivalent to the predicate devices in terms of intended use, design, material, function, mechanism of action, clinical utility, manufacturing and sterilizationprocess. The testing conducted to assess the packaging modifications includes performance assessment per the following recognized standards:

Table 4: Performance Standards

Standard	Description
ISO 11135-1:2007	Sterilization of health care products Ethylene Oxide Part 1
ISO 10993-1:2009	Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing
ISO 10993-7:2008	Biological Evaluation of Medical Devices Part 7: Ethylene oxide sterilization residuals
ISO 14971: 2012	Medical Device – Application of Risk Management to Medical Devices
HE75 : 2009	Human Factors Engineering – Design of Medical Devices
ISO11607-1: 2009	Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 10993-5:2009	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity

Bench Testing

There were no changes made that affect the AGILITY and NEUROSCOUT steerable guidewires' intended use, operational principle, design principle, materials, manufacturing or sterilization processes. The modifications proposed in this submission are for the packaging only. Therefore, design verification and validation of the devices was not warranted.

Verification and validation activities were focused on demonstrating package integrity of the proposed pouches. Appropriate testing was identified based on a review of the products' risk analyses and previous use of the new pouch materials. Testing was conducted as appropriate for the inclusion of the proposed pouches based on current standards, and all testing was performed on final sterile product.

The following testing was conducted:

Packaging Validation

- Visual Inspection
- Dye Leak
- Seal Strength

Sterilization Validation

- EO/ECH Residuals

Sterile Pouch Shelf-Life Stability Validation

- Visual Inspection
- Dye Leak
- Seal Strength

Biocompatibility Testing

- In vitro Cytotoxicity

I. Animal Testing

No animal studies were required as appropriate verification and validation of the packaging modifications were achieved based on the similarities of the proposed device to the predicate device, and from results of bench testing.

J. Summary of Clinical testing:

No clinical studies were required as appropriate verification and validation of the packaging modifications were achieved based on the similarities of the proposed device to the predicate device, and from results of bench testing.

Conclusion:

Based upon the design, materials, function, intended use, and the non-clinical testing performed by Codman it is concluded that the proposed packaging for the AGILITY® and NEUROSCOUT® Steerable Guidewire is substantially equivalent to the current AGILITY® and NEUROSCOUT® Steerable Guidewire (K121776), and therefore, does not raise any new questions of safety and effectiveness.

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

February 24, 2014

Codman & Shurtleff, Inc.
% Ms. Hannah Foley
Regulatory Affairs Specialist II
Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, MA 02767

Re: K133625
Trade/Device Name: AGILITY and NEUROSCOUT Steerable Guidewires
Regulation Number: 21 CFR 870.1330
Regulation Name: Neurovascular Catheter Guide Wire
Regulatory Class: Class II
Product Code: MOF
Additional Procode: DQX
Dated: January 28, 2014
Received: January 29, 2014

Dear Ms. Foley,

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 contact 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K133625

Device Name
AGILITY® Steerable Guidewire, NEUROSCOUT® Steerable Guidewire

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Carlos L. Pena -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."