K101339

Medtronic

AUG 31 2010

5. 510K SUMMARY

Submitter:	Medtronic Vascular 3576 Unocal Place Santa Rosa, CA 95403 U.S.A.
Contact Person:	Colleen Mullins Sr. Regulatory Affairs Specialist (978) 739-3267
Date Prepared:	May 6th, 2010
Trade Name:	Archer Super Stiff Guidewires
Common Name:	Guidewire
Classification Name:	Wire, Guide, Cardiovascular
Class:	21 CFR 1330, Product Code DQX
Product Code:	DQX
Predicate Device(s):	Cook Lunderquist Wire Guide (K061670) Boston Scientific Corporation Back-Up Meier Steerable Guidewire (K020283)
Device Description:	The Medtronic Archer Super Stiff Guidewire is a PTFE coated stainless steel guidewire. The Archer Super Stiff Guidewire is offered in 200cm and 260cm lengths and incorporates a flexible tip section and inner 8cm radiopaque spring for enhanced visibility. The Archer Super Stiff guidewire is offered in single and double curve tip configurations. The Archer Super Stiff guidewire is sterile, non-pyrogenic, disposable and for single use only
Statement of Intended Use:	The Medtronic Archer 0.035 inch (0.89 mm) Super Stiff Guidewires are indicated to facilitate catheter placement and exchange during diagnostic or interventional

procedures, where increased support, distal flexibility, and low surface friction of the guidewire is needed

Summary of Technological Characteristics:

All configurations of the Archer Super Stiff Guidewire have the same distal spring construction with an inner radiopaque spring and an outer spring. The springs are attached to the corewire. The Archer Super Stiff Guidewires have a nominal 0.035" OD and are available in 200 cm and 260 cm lengths with either a single or double curve tip configuration. The entire device is PTFE coated.

The Archer Super Stiff Guidewire has similar materials of construction to the predicate devices. It also has the same technological characteristics as the predicate devices as shown in the table below.

Characteristic	Archer Endovascular Guidewire (This 510k)	Cook Lunderquist Wire Guides (K061670)	BSX Back-up Meier Guidewire (K020283)
Diameter	0.035"	0.035"	0.035"
Length	200 cm 260 cm	260 cm 300 cm	185-300 cm
Tip Configuration	Single J or Double J curve	Straight, Single J or double J	Straight, Angled
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide

Summary of Non-Clinical data:

Non-clinical verification and validation of the Archer Super Stiff Guidewire consists of the following *in vitro* bench tests that were performed on the Archer Super Stiff Guidewire.

In vitro Bench Tests
Dimensions-OD-Tip Joint
Dimensions-OD-Proximal Joint
Dimensions-OD-Distal Spring
Dimensions-OD-Corewire
Dimensions-Overall Length
Dimensions-Tip Width
Dimensions-Out of Plane
Dimensions-Radiopaque Length

In vitro Bench Tests
Tip Stiffness
Tip Integrity-Torsional
Tip Integrity-Strength
PTFE Coating Adhesion-Corewire and springs
3 Point Bend Stiffness-Proximal

Biocompatibility testing was also performed per the requirements of ISO 10993-1 on the Archer Super Stiff Guidewire as listed below:

Biocompatibility Tests
IS0 Cytotoxicity Study
IS0 Maximization Sensitization Study
IS0 Intracutaneous Study
ISO/USP Systemic Toxicity Study
USP Material Mediated Pyrogen Study
ASTM Hemolysis Study
Compliment Activation (C3a & SC5b-9)
in Vivo Thromboresistance Study

In addition shelf life testing (product and packaging) and *in-vivo* pre-clinical (Animal Study) testing was performed on the Archer Super Stiff guidewire.

The Non-Clinical test results verify that the Archer Super Stiff Guidewire is substantially equivalent to the predicate devices and is adequate for its intended use

Conclusion from Data:

The Archer Super Stiff Guidewire is substantially equivalent in intended use, materials, technological characteristics and performance of the predicates wires, the Cook Lunderquist Wire Guide (K061670) and Boston Scientific Corporation Back-Up Meier Steerable Guidewire (K020283).

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

Medtronic Vascular
c/o Ms. Colleen Mullins
Senior Regulatory Affairs Specialist
37 A Cherry Hill Drive
Danver, MA 01923

AUG 31 2010

Re: K101339
Trade/Device Name: Medtronic Archer Super Stiff Guidewires
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guidewire
Regulatory Class: Class II (two)
Product Code: DQX
Dated: July 20, 2010
Received: July 21, 2010

Dear Ms. Mullins:

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 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 (240) 276-3150 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

Medtronic

Indications for Use

510(k) Number (if known): K 101339

Device Name: **Medtronic Archer Super Stiff Guidewires**

Indications for Use:

The Medtronic Archer 0.035 inch (0.89 mm) Super Stiff Guidewires are intended to facilitate catheter placement and exchange during diagnostic or interventional procedures in the aorta, where increased support, distal flexibility, and low surface friction of the guidewire is needed.

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)

K101339

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number _____