K123377

stryker®
Neurovascular

NOV 3 0 2012

510(k) Summary Of Safety And Effectiveness

Summary Date	October 31, 2012
Submitter Name and Address	Stryker Neurovascular 47900 Bayside Parkway Fremont, CA. 94538
Contact Person:	Rhoda M. Santos Regulatory Affairs Project Manager Phone: 510 413-2269 Fax: 510 413-2588 Email: rhoda.santos@stryker.com
Trade Name:	Target® Detachable Coils
Common Name:	Occlusion Coil, Vascular Occlusion Coil, Neurovascular Occlusion Coil
Classification Name:	Target Detachable Coils are classed as vascular and neurovascular embolization devices under 21 CFR 870.3300 (KRD) and 21 CFR 882.5950 (HCG), respectively, and are Class II devices (special controls). The special control for the devices is FDA's guidance document, *Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices* (issued 29 Dec 2004).

Legally Marketed Predicate Devices:

Reference (Clearance Date)	Device
K102672 (15 October 2010)	Target Detachable Coil
K112385 (15 September 2011)	Target Detachable Coil
K113412 (13 December 2012)	Target Detachable Coil

Device Description:

Stryker Neurovascular's **Target Detachable Coils** are comprised of four coil types: **Target Coil 360 STANDARD, Target Coil 360 SOFT, Target Coil 360 ULTRA** and **Target Coil HELICAL ULTRA**. All Target Coils are stretch resistant coils. Target Coils incorporate a length of multi-strand material through the center of the coil designed to help resist stretching. Target Coils are designed for use with Stryker Neurovascular's InZone™ Detachment System (sold separately).

Each Target Coil type consists of a platinum-tungsten alloy coil attached to a stainless steel delivery wire. For Target Coil 360 STANDARD, Target Coil 360 SOFT and Target Coil 360 ULTRA coils ≥ 2mm, the distal end of the main coil is formed such that there is a smaller distal loop at the end of the main coil to facilitate placement of the coil. The diameter of the distal loop is 75% that of the rest of the main coil loops.

Stryker Neurovascular's InZone Detachment System is intended for use with all Stryker Neurovascular Detachable Coils in the embolization of intracranial aneurysms and other vascular malformations of the neuro and peripheral vasculature.

The modifications described within this Special 510(k) have resulted in 70 new coil sizes to be added to the currently approved Target Coil product family. These 70 new UPNs use the same processes as the current Target Detachable Coil products with the only difference being the addition of a tapering process to taper the profile of a larger primary coil of 0.014 inches prior to assembly with the delivery wire for new coil sizes designated as Target XL Detachable Coils.

Verification Testing: Verification testing of the modified Target Detachable Coil consisted of the following:

Predicate Device Testing (from **K102672**)

1) Functional testing to assess:

Main Junction Tensile Strength
Delivery Wire Tensile Strength
Coil Detachment Time

2) MR Compatibility testing to assess:

Magnetically induced displacement (ASTM F2052)
Magnetically induced torque (ASTM 2213)
Magnetically induced heating effect (in 1.5 T and 3 T MR systems - ASTM F2182)
MR induced image artifact (ASTM F2119)

As a result of MR compatibility testing, the Directions for Use (DFU) for the Target Detachable Coil has been revised to include a more comprehensive MR Conditional statement describing the conditions under which the device was tested.

3) Pre-clinical testing to provide post-implant MR artifact data and to assess and compare the modified Target Detachable Coil to control coils in coiled aneurysm models.

4) Confirmatory biocompatibility testing as follows:

MEM Elution Cytotoxicity
Hemolysis, Direct Contact
USP Physico-Chemical <661>

5) Assessment of the new grade stainless-steel by Boston Scientific's Coporate Toxicology group.

Predicate Device Testing (from **K112385**)

1) Functional Testing to assess:

a) Coil / Catheter Compatibility
b) Product Removal from the Flushing Dispenser Coil (Product Removal Test Method, No Twistlock)

2) Packaging Verification testing to assess the ability of the new introducer sheath to protect the finished device

3) Shelf Life Testing, following climatic conditioning and distribution simulation, to assess the ability of the new introducer sheath to protect the finished device

4) Confirmatory biocompatibility testing as follows:

a) Cytotoxicity, MEM Elution (EN ISO 10993-5:2009)
b) Sensitization, Guinea Pig Maximization (EN ISO 10993-10:2009)
c) Intracutaneous Reactivity (EN ISO 10993-10:2010)
d) Acute Systemic Injection (EN ISO 10993-11:2009)
e) Rabbit Pyrogen, Materials Medicated (EN ISO 10993-11:2009)
f) Hemolysis, Direct Contact ((EN ISO 10993-4:2009)
g) Partial Thromboplastin Time (EN ISO 10993-4:2009)
h) In Vitro Hemocompatibility (EN ISO 10993-4:2009)
i) Complement Activation (EN ISO 10993-4:2009)
j) USP Physico-Chemical <661>
k) Latex Testing (ASTM D6499-07)

5) Design Validation testing in which a physician assessed the new introducer sheath and new retention clip for the ability of the new configuration to:

a) protect the finished device
b) provide acceptable introducer sheath friction
c) provide for proper hydration of the finished devicde within the new introducer sheath
d) enable easy removal of the finished device from the dispenser coil

Physician evaluation also assessed whether the revised DFU was clear, legible and easy to read.

Predicate Device Testing (from **K113412**)

1) Functional Testing to assess:

a) Main Junction Tensile Strength
b) Delivery Wire Tensile Strength

Testing for modifications that are the subject of this submission

1) Functional Testing to assess mechanical properties impacted by the use of the larger primary coil OD (0.014 inches):

a) Main Junction Tensile Test
b) Durability Challenge Test
c) Coil / Catheter Compatibility

2) Packaging Verification testing to assess the ability of the packaging to protect the finished device

3) Confirmatory biocompatibility testing as follows:

a) Cytotoxicity, MEM Elution (EN ISO 10993-5:2009)
b) Hemolysis, Direct Contact (EN ISO 10993-4:2009)
c) USP Physico-Chemical <661>
d) Fourier Transform Infrared Spectroscopy (FTIR) (EN ISO 10993-18:2009)

Accessories:

Target Detachable Coils are packaged within a flushing dispenser coil assembly. The dispenser coil is an accessory item with an attached flushport used to hydrate the coil prior to use.

Indications for Use /

Target Coils are indicated for endovascular embolization of:

- Intracranial aneurysms
- Other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae
- Arterial and venous embolizations in the peripheral vasculature

Comparison to Predicate Device:

Target Detachable Coils

Stryker Neurovascular's Target Detachable new coil sizes have the same intended use/indications for use as the predicate Target Detachable Coils.

Although an additional 70 new UPNs are being added to the Target coil product family to include larger and longer coil sizes with maximum secondary outer diameters (OD) up to 24mm and coil lengths up to 50cm, the modifications do not alter the intended use, indications for use, or the fundamental scientific technology of the predicate devices.

Risk assessment of the modifications in the form of design and use failure modes and effects analysis (design and use FMEAs) has been conducted in accordance with EN ISO 14971 :2012.

Stryker Neurovascular has determined the modifications to the predicate devices raise no new questions of safety or effectiveness.

Verification testing has demonstrated the modified Target Detachable Coils are substantially equivalent to the predicate Target Detachable Coils.

Conclusion:

Because the subject modifications do not alter the intended use or indications for use of the predicate devices, or the fundamental scientific technology of the predicate devices; and because risk assessment of the modifications and successful verification testing raise no new questions of safety and effectiveness, Stryker Neurovascular has determined the modified Target Detachable Coils to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 30, 2012

Stryker Neurovascular
c/o Ms. Rhoda Santos
Regulatory Affairs Project Manager
47900 Bayside Parkway
Fremont, CA 94538

Re: K123377
Trade/Device Name: Target Detachable Coil
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular embolization device
Regulatory Class: Class II
Product Code: HCG and KRD
Dated: October 31, 2012
Received: November 1, 2012

Dear Ms. Rhoda Santos:

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,

Quynh T. Hoang for:

Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123377

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Prescription Use __√_____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (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)

Quynh T. Hoang

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

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