DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 22, 2016

Stryker Neurovascular
Ms. Kate Taylor
Staff Regulatory Affairs Specialist
47900 Bayside Parkway
Fremont, California 94538

Re: K161429
Trade/Device Name: Target Detachable Coils
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG, KRD
Dated: May 20, 2016
Received: May 23, 2016

Dear Ms. Kate Taylor:

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 Industry and Consumer Education 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 Industry and Consumer Education 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 below.

510(k) Number *(if known)*
K161429

Device Name
Target Detachable Coils

Indications for Use *(Describe)*

Target Detachable Coils are intended to endovascularly obstruct or occlude blood flow in vascular abnormalities of the neurovascular and peripheral vessels.

Target Detachable 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

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Summary Date: May 20, 2016

Submitter Name and Address:
Stryker Neurovascular
47900 Bayside Parkway
Fremont, CA. 94538

Contact Person:
Kate Taylor
Staff Regulatory Affairs Specialist
Phone: 510 413-2175
Email: kate.taylor@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:

Primary Predicate
K153658 Target Detachable Coils (cleared 19 May 2016)

Reference Predicates
K123377 Target Detachable Coils (cleared 30 November 2012)
K093142 Target Detachable Coils (cleared 04 Feb 2010)
K102672 Target Detachable Coils (cleared 15 October 2010)
K112385 Target Detachable Coils (cleared 15 September 2011)
K113412 Target Detachable Coils (cleared 13 December 2012)

Device Description: Stryker Neurovascular **Target Detachable Coils** are comprised of the following coil types:

Target 360 Nano	Target Helical Nano	Target XL 360 Soft
Target 360 Ultra	Target Helical Ultra	Target XL 360 Standard
Target 360 Soft		Target XL Helical
Target 360 Standard		Target 3D

Device Description: ***(continued)***

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 the Stryker Neurovascular 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 Coils in the 360-shape, 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.

The Stryker Neurovascular 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.

Comparison to the Predicate Device:

Target Detachable Coils

This 510(k) requests clearance of 8 new Target Detachable Coil UPNs – *Target XXL 360 Detachable Coils*. The change which differentiates the Target XXL 360 Coils from the rest of the Target Detachable Coil product family is a new, larger primary coil OD (0.017 inches), as compared to current range of Target Coils primary coil ODs (0.010 - 0.014 inches). The larger primary coil OD of the Target XXL 360 Detachable Coils necessitates minor dimensional increase to the ID of the introducer sheath, which is a component of the packaging hoop and facilitates introduction into the microcatheter. The new introducer sheath is made of the same high density polyethylene material as the current introducer sheath, but uses a different pigment to color the sheath to provide differentiation from other Target Coils. The larger primary OD requires that the Target XXL Coil be used with the larger of the microcatheters recommended for all other Target Coils: maximum internal diameter 0.48 mm [0.019 in].
The new UPNs utilize the same design and materials of existing Target Coils, and the same manufacturing, packaging and sterilization processes.

The modified Stryker Neurovascular Target Detachable Coils have the same intended use/indications for use as the predicate Target Detachable Coils.

The modifications to the Target Detachable Coils 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.

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

Test	Test Method Summary/Purpose	Results
Dimensions	Coil Secondary Diameter and 2D Loop Secondary Diameter are measured.	Met the same criteria as the predicate device.
Visual	Visual confirmation that the entire coil is contained within the introducer sheath.	
Durability	The coil is visually inspected for damage and Main Junction Tensile Strength is tested after simulated deployment/retraction in a tortuous model.	Met the same criteria as the predicate device.
Particulates	Particulate release due to delivery of the coil is measured.	Met the same criteria as the predicate device.
Friction	Frictional force through an introducer sheath and a compatible microcatheter is measured.	Met the same criteria as the predicate device.
Biocompatibility	• MEM Elution Cytotoxicity/Part 5 • Hemolysis Direct/Extract Contact/Part 4 • USP Physicochemical USP <661> • FTIR/Part 18 • Natural Rubber Latex	Met the same criteria as the predicate device.
Packaging	Assess the ability of the packaging system to protect the finished device.	Met the same criteria as the predicate device.
Simulated Use	• Coil conformability • Coil durability during repositioning • Microcatheter compatibility • Coil friction during delivery through the microcatheter • Introducer sheath friction acceptability • Removal of coil from the packaging hoop without damaging the device	Met the same criteria as the predicate device.

Accessories: Target Detachable Coils are not packaged with any accessories.

Intended Use / Indications for Use

Intended Use/Indications for use

Target Detachable Coils are intended to endovascularly obstruct or occlude blood flow in vascular abnormalities of the neurovascular and peripheral vessels.

Target Detachable 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

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.