December 14, 2022

Stryker Neurovascular
Jonathan Bemben
Staff Regulatory Affairs Specialist
47900 Bayside Parkway
Fremont, California 94538

Re: K222533
Trade/Device Name: Target Tetra Detachable Coils
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG, KRD
Dated: November 10, 2022
Received: November 14, 2022

Dear Jonathan Bemben:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Naira Muradyan -S

Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
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OHT5: Office of Neurological
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222533

Device Name
Target Tetra™ Detachable Coils

Indications for Use *(Describe)*

Target Detachable Coils are intended to endovascularly obstuct 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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Submitter: Stryker Neurovascular
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Contact: Jonathan Bemben
Tel (651) 202-8121
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Date Prepared: December 14, 2022

Device Trade Name: Target Tetra™ Detachable Coils

Classification Name: Target Detachable Coils are 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:

Predicate Devices	
K153658 (Cleared 19-May-2016) **K161429** (Cleared 22-June-2016)	Target Detachable Coils

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 3D	Target XL Helical
Target 360 Standard	Target XXL 360	Target Tetra (Subject Device)

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 with the Tetrahedral shape, the distal end of the main coil is formed such that the diameter of the distal loop is approximately 75% that of the overall secondary outer diameter (OD) size.

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.

INTENDED USE / INDICATION 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

COMPARISON TO THE PREDICATE DEVICE: TARGET DETACHABLE COILS

The change which differentiates the Target Tetra Detachable Coils from the rest of the Target Detachable Coil product family is a new secondary shape, a modified stretch resistant fiber configuration and a modified link design as compared to the current range of Target Detachable Coils.

The Target Tetra Detachable Coils share the same intended use, indications for use, and fundamental scientific technology as the predicate devices. A comparison of the subject device with the predicate devices is summarized in **Table 1** below.

Table 1. Substantial Equivalence Comparison

Characteristic	Target Detachable Coils (predicate devices K153658 and K161429)	Target Tetra Detachable Coils (subject device K222533)
Manufacturer	Stryker	Same
Trade Name	Target Detachable Coils	Target Tetra™ Detachable Coils
Device Type	Vascular Embolization Device; Neurovascular Embolization Device	Same
Classification Regulation (21 CFR)	870.3300, Class 2 882.5950, Class 2	Same
Product Code:	KRD, HCG	Same
Intended Use/Indication 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	Same
How Supplied	Single Use/Sterile	Same
Method of Sterilization	Ethylene Oxide (EtO) Gas	Same
Coil Material	• Platinum/Tungsten alloy	Same
Delivery Wire Material	• Stainless steel	Same
Features		
Primary Wire Outer Diameter	0.00125 in – 0.003 in (0.032 mm – 0.076 mm)	Target Tetra fits within the range of currently offered Target Detachable Coils and utilizes a Primary Wire Outer Diameter of 0.00125 in

Primary Coil Wind Outer Diameter	0.010 in – 0.017 in (0.254 mm – 0.432 mm)	Target Tetra fits within the range of currently offered Target Detachable Coils and utilizes a Primary Coil Wind Outer Diameter of 0.010 in
Secondary Coil Outer Diameter	1 mm – 24 mm	Target Tetra fits within the range of currently offered Target Detachable Coils and utilizes a range of Secondary Coil Outer Diameters of 1.5 mm – 4.5 mm

Characteristic	Target Detachable Coils (predicate devices K153658 and K161429)	Target Tetra Detachable Coils (subject device K222533)
Coil Length	1 cm – 50 cm	Target Tetra fits within the range of currently offered Target Detachable Coils and utilizes a Coil Length range of 2.0 cm – 10.0 cm
Coil Secondary Shape Types	Helical, 360, 3D	Tetrahedral
Power Supply Compatibility	InZone® Detachment System	Same
Packaging Configuration and Materials	**Pouch:** Tyvek/Film pouch **Carton:** Chipboard carton **Dispenser coil (Hoop):** HDPE tubing and clips	Same

RISK ASSESSMENT

Risk assessment has been conducted for the subject device in accordance with EN ISO 14971:2019. Stryker Neurovascular has determined that no new questions of safety or effectiveness are raised when compared to the predicate devices. This line extension does not result in any new failure modes nor were there any changes to existing failure modes.

PERFORMANCE DATA - BIOCOMPATIBILITY TESTING

The subject device was evaluated for biocompatibility using EN ISO 10993-1:2020 and FDA guidance documents. All materials of the subject device have an established history of safe use from the predicate devices and there are no novel materials or processes used. Confirmatory chemical characterization testing was performed on the subject device using Fourier-transform infrared spectroscopy (FTIR) and physicochemical evaluation to determine substantial equivalence to the predicate devices. From the evaluation performed, the previously conducted biocompatibility testing for the predicate devices is deemed applicable for the subject device.

PERFORMANCE DATA - BENCH TESTING

Performance bench testing has demonstrated that the Target Tetra Detachable Coils are substantially equivalent to the predicate devices and do not raise new questions of safety or effectiveness.

Performance bench testing of the Target Tetra Detachable Coils consisted of the following tests listed in **Table 2**.

Table 2. Performance Bench Testing

Test	Test Method Summary/Purpose	Conclusions
Tipball Attachment	Use tensile tester to tensile test the tipball. Place tipball in flow test setup. Visually inspect tipball to ensure it is attached to the main coil after being subjected to pre-loading and flow test conditions.	Met acceptance criteria
Durability	The coil is visually inspected for damage and main junction tensile strength is tested after simulated deployment/retraction in a tortuous model.	Met acceptance criteria
Particulates	Particulate release due to delivery of the coil is measured.	Particulate characterization was acceptable
Friction	Frictional force through an introducer sheath and a compatible microcatheter is measured.	Met acceptance criteria
Packaging	Assess the ability of the packaging system to protect the finished device.	Met acceptance criteria
Simulated Use	• Microcatheter Compatibility • Main Coil Softness (Coil Conformability) • Sheath Friction • Aneurysm Frame and Fill • Coil Framing Ability • Coil Stretch Resistance [SR] • Coil Durability During Repositioning • Main Junction Interaction with Microcatheter during Alignment • Intended Use Environment • Labeling Requirements • Device Visibility under Fluoroscopy	Design validation testing met acceptance criteria

PERFORMANCE DATA – ANIMAL STUDY

No animal study was conducted because bench testing was determined sufficient to support substantial equivalence to the predicate device.

PERFORMANCE DATA – CLINICAL STUDY

No clinical study was conducted because bench testing was determined sufficient to support substantial equivalence to the predicate device.

ACCESSORIES

Target Tetra Detachable Coils are not packaged with any accessories.

CONCLUSION

The Target Tetra Detachable Coils share the same intended use, indications for use, and fundamental scientific technology as the predicate devices, Target Detachable Coils. Additionally, risk assessment of the modifications raises no new questions of safety and effectiveness and successful verification and validation testing demonstrated that the device functions as intended. Therefore, Stryker Neurovascular has determined the Target Tetra Detachable Coils to be substantially equivalent to the predicate devices.