June 24, 2026

Stryker Neurovscular
Zach Borla
Senior Staff Regulatory Affairs Specialist
47900 Bayside Pkwy.
Fremont, California 94538

Re: K261772
Trade/Device Name: Target Xtra Detachable Coil
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG, KRD
Dated: May 28, 2026
Received: May 29, 2026

Dear Zach Borla:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

SARA S. THOMPSON -S

Sara S. Thompson, D.V.M.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261772

Please provide the device trade name(s).

Target Xtra Detachable Coil

Please provide your Indications for Use below.

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

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

Date Prepared: June 24, 2026

Submitter: Stryker Neurovascular
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Contact: Mr. Zach Borla
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Device Trade Name: Target Xtra Detachable Coil

Classification Name: Target Xtra 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 device is FDA's guidance document, *Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices* (issued 29 Dec 2004).

Legally Marketed Predicate Device: K252694 (Cleared 11 Dec 2025)

DEVICE DESCRIPTION

Target Xtra Detachable Coil is a stretch resistant, electrolytically detachable coil consisting of a platinum-tungsten alloy coil attached to a stainless-steel delivery wire.

Target Xtra Detachable Coil is specifically designed for use with Stryker Neurovascular InZone® Detachment System (sold separately).

Target Xtra Detachable Coil is compatible with Stryker Neurovascular 2-tip marker microcatheters; refer to Instructions for Use (IFU) for the compatible microcatheter size.

ACCESSORIES

Target Xtra Detachable Coil is not packaged with any accessories.

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 COIL

Target Xtra Detachable Coil, is a line extension of the predicate device, Target Detachable Coil (family), that combines existing helical and tetrahedral secondary shapes in a single coil configuration and incorporates a modified stretch resistant fiber into the main coil.

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

Table 1. Substantial Equivalence Comparison

Characteristic	Predicate Device K252694	Subject Device
Manufacturer	Stryker	Same
Trade Name	Target Detachable Coil	Target Xtra Detachable Coil
Device Type	Vascular Embolization Device; Neurovascular	Same

Stryker Neurovascular
510(k) Premarket Notification, Special 510(K)
Target Xtra Detachable Coil

Characteristic	Predicate Device K252694	Subject Device
	Embolization Device	
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 embolization's 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		
Secondary Coil Outer Diameter	1 mm – 24 mm	Target Xtra fits within the range of currently offered Target Detachable Coils and utilizes a Secondary Coil Outer Diameter of 1.5–3 mm.
Coil Length	1 cm – 50 cm	Target Xtra fits within the range of currently offered Target Detachable Coils and utilizes a Coil Length of 8–32 cm.
Coil Secondary Shape Types	360, 3D, Helical, Tetrahedral	Helical-Tetrahedral Combination
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, "*Medical devices — Application of risk management to medical devices*." Stryker Neurovascular has determined that no new questions of safety or effectiveness are raised when compared to the predicate device. This line extension does not result in any new or modified risks.

BIOCOMPATIBILITY

No changes have been made to the materials or manufacturing processes used for the subject device. No new or additional biological risks have been identified. Therefore, the previously completed biocompatibility testing for the predicate device remains applicable and supports the biological safety of the subject device.

PERFORMANCE TESTING – BENCH TESTING

Performance bench testing has demonstrated that the Target Xtra Detachable Coil is substantially equivalent to the predicate device and does not raise new questions of safety or effectiveness.

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

Table 2. Performance Bench Testing

Test	Test Method Summary/Purpose	Conclusions
Main Coil Softness (Coil Conformability)	Simulated use testing was conducted in a neurovascular anatomy model.	Met acceptance criteria
Main Junction Tensile Strength	Use tensile tester to measure applied peak tensile force of the main junction.	Met acceptance criteria
Durability	Simulated use testing was conducted in a neurovascular anatomy model. The coil was visually inspected for fractures and damage after simulated deployment and retraction.	Met acceptance criteria
Particulate	Particulate release due to delivery and detachment of the coil was evaluated in a neurovascular anatomy model.	Particulate characterization was acceptable
Coil Friction through Microcatheter	Frictional force through a compatible microcatheter was evaluated in a neurovascular anatomy model.	Met acceptance criteria

PERFORMANCE TESTING – ANIMAL STUDY

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

PERFORMANCE TESTING – CLINICAL STUDY

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

CONCLUSION

The Target Xtra Detachable Coil shares the same intended use, indications for use, and fundamental scientific technology as the predicate device, Target Detachable Coil (family). 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 Xtra Detachable Coil to be substantially equivalent to the predicate device.