December 11, 2025

Stryker Neurovascular
Genae Tripp
Staff Regulatory Affairs Specialist
47900 Bayside Parkway
Fremont, California 94538-2588

Re: K252694
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: August 26, 2025
Received: August 26, 2025

Dear Genae Tripp:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252694

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Date Prepared: December 5, 2025

Submitter: Stryker Neurovascular
47900 Bayside Parkway
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Facility Registration #300853977

Contact: Genae Tripp
Staff Regulatory Affairs Specialist
Tel (805) 630-3378
E-mail: genae.tripp@stryker.com

Device Trade Name: Target 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 Device: K242243 (Cleared 29 Aug 2024)

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

Please note that all Target Detachable Coils referenced in this submission are considered the Subject Device.

Target Detachable Coils are stretch resistant, electrolytically detachable coils consisting of a platinum-tungsten alloy coil attached to a stainless steel delivery wire.

Target Detachable Coils are specifically designed for use with Stryker Neurovascular's InZone® Detachment System (sold separately).

Target Detachable Coils are compatible with Stryker Neurovascular 2-tip marker microcatheters; refer to Instructions for Use (IFU) for the compatible microcatheter sizes.

COMPARISON TO THE PREDICATE DEVICE: TARGET DETACHABLE COILS

This 510(k) requests clearance for the revised Instructions for Use to support the use of Target Detachable Coils via transradial access in addition to the existing use via transfemoral access.

A comparison of the subject device with the predicate device is summarized in **Table 1** below.

Table 1. Substantial Equivalence Comparison

Characteristic	Predicate Device K242243	Subject Device
Manufacturer	Stryker	Same
Trade Name	Target Detachable Coil	Same
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 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	Same
Coil Length	1 cm – 50 cm	Same
Coil Secondary Shape Types	Helical, 360, 3D, Tetrahedral	Same
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

ACCESSORIES

Target Detachable Coils are not packaged with any accessories.

INTENDED USE / INDICATIONS FOR USE:

Intended Use:

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

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

BIOCOMPATIBILITY

The biocompatibility profile of the products remains unchanged, and previous biocompatibility assessments remain applicable.

PERFORMANCE TESTING

Bench Testing

Non-clinical bench testing was performed to assess the tracking and deployment performance of Target Detachable Coils through radial access, and to compare these results with femoral access using clinically representative access models.

Parameter	Results
Microcatheter Friction	No noticeable difference between radial access and femoral access
Ease of Deployment	No noticeable difference between radial access and femoral access
Ease of Retraction	No noticeable difference between radial access and femoral access
Any noticeable difference in device behavior	No noticeable difference between radial access and femoral access
Track Force Testing – Advance Force	No statistical difference between radial access and femoral access
Track Force Testing – Pullback Force	No statistical difference between radial access and femoral access

CONCLUSION

Because the proposed changes to the subject device do not alter the intended use or indications for use of the predicate device, nor its fundamental scientific technology, and the risk assessment of these changes raises no new questions regarding safety and effectiveness, Stryker Neurovascular has determined that the proposed change to the subject device is substantially equivalent to the predicate device.