October 17, 2025

Stryker Neurovascular
Lorraine Mazzeo
Staff Regulatory Affairs Specialist
47900 Bayside Parkway
Fremont, California 94538

Re: K251832
Trade/Device Name: InZone IST Detachment System; IZDS Connecting Cable
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG, KRD
Dated: September 19, 2025
Received: September 19, 2025

Dear Lorraine Mazzeo:

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, DVM
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

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)*
K251832

Device Name
InZone IST Detachment System; IZDS Connecting Cable

Indications for Use *(Describe)*

The InZone IST Detachment System is intended for use with all versions of Stryker Neurovascular embolization devices in the embolization of intracranial aneurysms and other vascular malformations of the neuro and 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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Date Prepared:	October 17, 2025
Submitter:	Stryker Neurovascular 47900 Bayside Parkway Fremont, CA 94538 Facility Registration #3008853977
Contact:	Lorraine Mazzeo Staff Regulatory Affairs Specialist Tel (510) 413-2676 E-mail: lorraine.mazzeo@stryker.com
Device Trade Name:	InZone IST Detachment System and IZDS Connecting Cable
Indications for Use/Intended Use:	The InZone IST Detachment System is intended for use with all versions of Stryker Neurovascular embolization devices in the embolization of intracranial aneurysms and other vascular malformations of the neuro and peripheral vasculature.
Classification Name:	The InZone IST Detachment System is a vascular and neurovascular embolization device under 21 CFR 870.3300 (KRD) and 21 CFR 882.5950 (HCG), respectively, and is a Class II device (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:

Predicate Device
K212455 (Cleared 16-Nov-2021)

Device Description

Stryker Neurovascular's InZone IST Detachment System is a sterile, handheld, single-patient use device designed for use with Stryker Neurovascular embolization devices. The device consists of an enclosure with a detachment button, five LED indicator lamps, a funnel inset at its distal end, and a cable connection port. The device comes pre-loaded with two AAAA (1.5 VDC) batteries.

Stryker Neurovascular's IZDS Connecting Cable is a 180 cm cable intended for use with the InZone IST Detachment System in the detachment of monopolar embolization devices. The cable completes the connection between the InZone IST unit and a patient return electrode (a 20 or 22 gauge uncoated stainless-steel hypodermic needle) inserted subcutaneously at the patient's groin.

How the Device Functions

Use of Stryker Neurovascular embolization devices involves a minimally invasive procedure to access the treatment area (intracranial aneurysm or other neuro or peripheral abnormality) from within a blood vessel (endovascular therapy). Treatment involves insertion of a microcatheter into a patient's femoral artery and then navigation of the microcatheter through the vascular system, into the neuro or peripheral vasculature, and then to the site of the lesion.

Stryker Neurovascular embolization devices are used in conjunction with:

• Stryker Neurovascular's InZone IST Detachment System

• Stryker Neurovascular's IZDS Connecting Cable, and

• a Patient Return Electrode (an off-the-shelf 20 or 22-gauge stainless-steel hypodermic needle)

The InZone IST Detachment System and IZDS Connecting Cable are sold separately.

During a procedure, a physician will assess the target lesion to determine the type, size, and the number of embolization devices to use. After prepping the patient and preparing the embolization device according to the instructions for use, the embolization device is delivered through the microcatheter to the site of the lesion. The delivery wire enables the physician to deploy, position, or reposition the coil until proper placement. Prior to detachment of the embolization device, the entire device (i.e. embolization device and delivery wire) may be withdrawn completely, if necessary (e.g., if the physician desires to use a different size or shape embolization device).

After being placed at the site of the lesion, the embolization device is detached from its delivery wire through an electrolytic process using the InZone Detachment System.

Table 1: Compatibility between Stryker Neurovascular's InZone IST Detachment System and embolization devices

	Types of Stryker Neurovascular embolization devices that can be used
InZone IST Detachment System (IST345100960)	Monopolar Embolization Devices[1] Bipolar Embolization Devices[2]

[1] Requires use of Stryker Neurovascular's IZDS Connecting Cable, p/n M00345110250 (sold separately) with the InZone IST Detachment System.

[2] No cable required for embolization device detachment.

When using the InZone IST Detachment System to detach Stryker Neurovascular Monopolar Embolization Devices:

An IZDS Connecting Cable is used in conjunction with an off-the-shelf patient return electrode. The IZDS Connecting Cable (Model / UPN M00345110250) is a 180 cm ground cable (black) for use with the InZone IST Detachment System. There are no accessories provided with the IZDS Connecting Cable.

The proximal end of the embolization device's delivery wire is inserted into the InZone IST Detachment System (anode connection), and the IZDS Connecting Cable completes the circuit between the InZone IST Detachment System ground port and the patient return electrode (cathode connection).

The InZone IST Detachment System and IZDS Connecting Cable are sold separately.

When using the InZone IST Detachment System to detach Stryker Neurovascular Bipolar Embolization Devices:

No cable is required as the embolization device's delivery wire incorporates an anode and cathode into the wire thus eliminating the need to use a connecting cable and patient return electrode when detaching a Bipolar Embolization Device.

The proximal end of the embolization device's wire is inserted into the InZone IST Detachment System (anode connection); the device's delivery wire hypotube provides the current return path (cathode connection).

Scientific Concept

In the use of Stryker Neurovascular electrolytically detachable embolization devices, detachment of the embolization device from its delivery wire is accomplished by means of an electrolytic process wherein the body's electrolytes serve as the electrolytic carrier between positive and negative electrodes. Since body fluids are relatively ionic, these fluids serve as good conductors

for the minimal electric current generated by the InZone IST Detachment System. Electrolytically detachable embolization devices are designed so that electrolytic dissolution occurs in a defined area called the detachment zone.

Operation of the InZone IST Detachment System in the detachment of embolization devices is governed by the InZone IST's firmware first detecting the type of delivery which is inserted into the unit's funnel.

When used with Stryker Neurovascular Monopolar Embolization Devices, the InZone IST Detachment System operates at a maximum of 12 VDC power and a maximum current of 1.0 mA.

For Stryker Neurovascular Bipolar Embolization Devices, when the InZone IST Detachment System detects that a Bipolar Embolization Device delivery wire has been inserted into the unit's funnel, the device's firmware engages circuity which operates the device at a maximum of 28 VDC power and 2.4 mA of current.

Physical and Performance Characteristics

Description:	Sterile, hand-held, internally powered, disposable unit, used within sterile field
Size:	14.0 x 5.8 x 2.8 cm (5.5 x 2.3 x 1.1 inch)
Weight:	80 g (2.8 oz)
Power:	3V
Power Source:	Two 1.5 V (AAAA) DC batteries (in series)
CPU Operating Voltage:	3.3 VDC
Max Current:	When detaching Monopolar Embolization Devices: 1 mA When detaching Bipolar Embolization Devices: 2.4 mA
Power Switch:	Inserting coil delivery wire turns the unit on. Removing delivery wire turns the unit off. During use, if after 2 minutes the unit detects no activity, the unit will enter SLEEP MODE; pressing and releasing the DETACHMENT BUTTON will bring the system back to its previous state.
Safety Features:	At start up: Memory integrity (checksum assessment); calibration validity

	During detachment: Over-current / over-voltage (at least 10x/sec) Software consistently running (at least 100x/sec)
Delivery Wire Interface:	InZone IST slides over proximal 6.5 cm of embolization device delivery wire
Attachment to Patient Return Electrode (PRE):	When detaching Monopolar Embolization Devices: Black cable with minigrabber attached to PRE When detaching Bipolar Embolization Devices: Not applicable; return is integral to the device
Cable Socket Type:	1.5 mm recessed male on black safety-sheathed (touch-proof) socket (only for use when detaching Monopolar Embolization Devices)
Sterilization Method:	Ethylene Oxide Gas
Sterile Barrier:	PETG tray with Tyvek® lid
Packaging:	Carton with eIFU Pointer Page
User Serviceable Parts:	No user serviceable parts
User Required Maintenance:	No user required maintenance
Calibration:	Done at factory
Number of Detachments:	Minimum of 20 detachments

User Interface/Displays:

Display	**Comment/Action**
Power	System Ready Indicator (LED) on and single audible tone when powered up
Current Voltage	Current Flow Indicator (LED) on (green)
Cycle Complete	Cycle Complete Indicator (LED) on (solid green), 3 short beeps: For Stryker Neurovascular Bipolar Embolization Devices: InZone IST software has assessed that detachment has likely occurred.

	For Stryker Neurovascular Monopolar Embolization Devices: InZone IST has assessed a full cycle is complete in less than 75 seconds. Cycle Complete Indicator (LED) on (blinking green), 1 long beep: For Stryker Neurovascular Bipolar Embolization Devices: InZone IST software has assessed that detachment has likely not occurred For Stryker Neurovascular Monopolar Embolization Devices: InZone IST has assessed a full cycle is complete in 75 seconds.
Running	Current Flow Indicator (LED) on (solid green)
Low Battery	Low Battery Indicator (LED) on (blinking amber)
Grounding	Grounding Indicator (LED) on (blinking amber) until complete circuit is detected; when complete circuit is detected, LED will remain on (solid amber) and System Ready Indicator (LED) will turn on (solid green) accompanied by a single beep.
To start detachment	Press Detachment Button.
To initiate another detachment cycle	If CYCLE COMPLETE LED is lit, pressing and releasing the Detachment Button will initiate another cycle.
Error	All LEDs illuminate except CYCLE COMPLETE LED.

Packaging:

Each InZone IST Detachment System is packaged in a PETG tray. A Tyvek lid is heat-sealed onto the tray. The tray with lid is then placed into a paperboard carton along with the eIFU Pointer Page.

Verification Testing:

Verification testing of the InZone IST Detachment System consisted of the following:

1) Bench top testing to assess:
    a) Maximum Detachment Time
    b) Detachment Cycle Time
2) Risk assessment in accordance with ISO 14971 and Stryker Neurovascular Risk Management Planning SOP

3) Assessment of the modifications for impact upon:

Electrical Safety (no impact)
Electromagnetic Compatibility (no impact)
Sterility Assurance (no impact)
Shelf Life (no impact)
Packaging Verification (no impact)
Packaging Shelf Life (no impact)

Accessories:

There are no accessories to the InZone IST Detachment System

Comparison to Predicate Device:

This 510(k) is for modifications to the InZone Detachment System indications for use statement, marketed under a new Trade Name for the Subject Device, the InZone IST Detachment System.

As supported by the Design Verification testing, the data demonstrated that the generalized indications for use for the Subject Device do not affect the safety and effectiveness of the device when used as labeled. The modified indications for use do not alter the fundamental intended use. The Subject Device treats the same diseases or conditions in the same patient population as the Predicate Device. The Subject Device is still used for the electrolytic detachment of Stryker Neurovascular embolization devices and does not alter the intended therapeutic use of the device. Additionally, the device has the same technological characteristics (i.e., design, material, energy source) as the Predicate Device. There is no change to the fundamental Principle of Operation, which is electrolytic detachment.

Stryker Neurovascular's IZDS Connecting Cable has the same fundamental intended use as the current legally marketed Predicate Device cleared K212455. The cable is used in conjunction with the InZone IST Detachment System and is used for electrical grounding when detaching monopolar embolization devices to treat the same diseases or conditions in the same patient population as the Predicate Device. Additionally, the device has the same technological characteristics (i.e., design, material, energy source) as the Predicate Device.

	Risk assessment of the modifications, in the form of design failure modes and effects analysis (DFMEA), has been conducted in accordance with ISO 14971:2021. Stryker Neurovascular has determined the modifications to the Predicate Device raise no new questions of safety or effectiveness. Verification testing of the InZone IST Detachment System has demonstrated the device to be substantially equivalent to the Predicate InZone Detachment System cleared under K212455.
Conclusion:	Stryker Neurovascular has compared device materials, design, and performance to the predicate device. The Subject modifications do not alter the intended use of the Predicate Device or the fundamental scientific technology of the Predicate Device; and because risk assessment of the modifications and successful verification testing raise no new questions of safety and effectiveness, Stryker Neurovascular believes the InZone IST Detachment System to be substantially equivalent to the current legally marketed Predicate Device, InZone Detachment System, cleared in K212455.