November 16, 2021

Stryker Neurovascular
Breskella Halteh
Senior Manager, RAQA Compliance
47900 Bayside Parkway
Fremont, California 94538

Re: K212455
Trade/Device Name: InZone Detachment System
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG, KRD
Dated: August 27, 2021
Received: August 30, 2021

Dear Breskella Halteh:

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, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212455

Device Name
InZone® Detachment System

Indications for Use *(Describe)*
The InZone Detachment System is intended for use with all versions of Stryker Neurovascular detachable coils 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.

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

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Neurovascular

510(k) Summary

Summary Date	**November 15, 2021**
Submitter Name and Address	Stryker Neurovascular 47900 Bayside Parkway Fremont, CA 94538
Contact Person:	Breskella Halteh Senior Manager, RAQA Compliance Stryker Neurovascular Phone: 650 814 3781 (mobile) Email: breskella.halteh@stryker.com
Trade Name:	InZone® Detachment System
Common Name:	Power Supply
Indications for Use / Intended Use:	The InZone Detachment System is intended for use with all versions of Stryker Neurovascular detachable coils in the embolization of intracranial aneurysms and other vascular malformations of the neuro and peripheral vasculature.
Classification Name:	Stryker Neurovascular detachable coils are Class II devices (special controls) classed as neurovascular embolization devices under 21 CFR 882.5950 (HCG) and vascular embolization devices under 21 CFR 870.3300 (KRD). 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:	InZone Detachment System cleared under K160096 on 19 Feb 2016.

510(k) Summary

Device Description:

Stryker Neurovascular's InZone® Detachment System is a sterile, handheld, single-patient use device designed for use with Stryker Neurovascular Detachable Coils. 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.

How the Device Functions

Use of Stryker Neurovascular Detachable Coils 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 Stryker Neurovascular two tip-marker 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.

Detachable coils are used in conjunction with:

- Stryker Neurovascular microcatheters
- Stryker Neurovascular's InZone 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)

Microcatheters, InZone Detachment System and IZDS Connecting Cable are all sold separately.

During a procedure, a physician will assess the target lesion to determine the type, size and number of coils to use. After prepping the patient and preparing the coil according to the instructions for use, the coil 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 coil, the entire device (i.e., coil and delivery wire) may be withdrawn completely, if necessary (e.g., if the physician desires to use a different size or shape coil).

The radiopaqueness of the platinum-tungsten coil, in conjunction with radiopaque markers on the coil's delivery wire and on the microcatheter, enable the physician to properly position the device within the lesion and to always know the location of the coil relative to the distal tip of the microcatheter.

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

510(k) Summary

Table 1 - Compatibility between Stryker Neurovascular's InZone® Detachment System and Stryker Neurovascular Detachable Coils

	Types of Coils that can be used
InZone Detachment System (M00345100950)	GDC Detachable Coils[1] Target Detachable Coils[2]

[1] Requires use of Stryker Neurovascular's IZDS Connecting Cable, p/n M00345110250 (sold separately) with the InZone Detachment System.
[2] No cable required for coil detachment.

When using the InZone Detachment System to detach GDC Detachable Coils:

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 Detachment System. There are no accessories provided with the IZDS Connecting Cable.

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

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

When using the InZone Detachment System to detach Target Detachable Coils:

No cable is required as the device's composite metal and polymer 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 Target Detachable Coil.

The proximal end of the coil's delivery wire is inserted into the InZone 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 Detachable Coils, detachment of the coil 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® Detachment System. Detachable Coils are designed so that electrolytic dissolution occurs in a defined area called the detachment zone.

510(k) Summary

Scientific Concept (cont.)

Operation of the InZone Detachment System in the detachment of coils is governed by the InZone device's firmware first detecting the type of delivery wire which is inserted into the unit's funnel**.**

When used with GDC Detachable Coils, the InZone Detachment System operates at a maximum 12VDC and a maximum current of 1.0 mA.

For Target Detachable Coils, when the InZone Detachment System detects that a Target Detachable Coil delivery wire has been inserted into the unit's funnel, the device's firmware engages circuitry which operates the device at a maximum 28VDC and 2.4 mA.

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 V DC
Max Current:	When detaching GDC Coils: 1mA When detaching Target Detachable Coils: 2.4 mA
Power Switch:	Inserting coil delivery wire turns unit on. Removing delivery wire turns unit off. During use, if after 2 minutes unit detects no activity, 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 slides over proximal 6.5 cm of coil delivery wire
Attachment to Patient Return Electrode (PRE):	When detaching GDC Coils: Black cable with minigrabber attached to PRE When detaching Target Detachable Coils: Not applicable; return is integral to the device.

510(k) Summary

Physical and Performance Characteristics (cont.)

Cable Socket Type:	1.5 mm recessed male on black safety-sheathed (touch-proof) socket (only for use when detaching GDC Detachable Coils)
Sterilization Method:	Ethylene Oxide Gas
Sterile Barrier:	PETG tray with Tyvek® lid
Packaging:	Carton with Directions for Use
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 Target Coils: InZone software has assessed that detachment has likely occurred. For GDC Coils: InZone has assessed a full cycle is complete in less than 75 seconds. Cycle Complete Indicator (LED) on (blinking green), 1 long beep: For Target Coils: InZone software has assessed that detachment has likely not occurred For GDC Coils: InZone 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.

510(k) Summary

Packaging:

Each InZone® 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 fiberboard carton along with Directions for Use.

Verification Testing:

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

1) Software (firmware) test case model as well as bench top testing to assess:

   a) detachment cycle time
   b) maximum detachment time
   c) detachment consistency
   d) detection consistency
   e) max voltage output
   f) max current output
   g) low battery detection
   h) fault detection at power up
   i) over voltage and over current detection
   j) data storage and retrieval capability
   k) delivery wire compatibility and detection
   l) button activation
   m) audio and visual signals

2) Software verification in accordance with EN 62304 and Stryker Neurovascular Design and Development Planning SOP

3) Risk assessment in accordance with ISO 14971 and Stryker Neurovascular Risk Management Planning SOP

4) 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 Detachment System.

510(k) Summary

Comparison to Predicate Device:

This 510(k) is for modifications to InZone Detachment System firmware to decrease detachment time when used with Target Coils and to update product labeling.

The modified InZone® Detachment System has the same intended use / indications for use as the current legally marketed predicate device cleared under premarket notification K160096.

Although the InZone Detachment System incorporates modifications to device firmware and device labeling and packaging, the modifications do not alter the fundamental scientific technology of 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 14971:2019. Stryker Neurovascular has determined the modifications to the predicate device raise no new questions of safety or effectiveness.

Verification testing of the modified InZone Detachment System has demonstrated the device to be substantially equivalent to the predicate InZone Detachment System cleared under K160096.

Conclusion:

Stryker Neurovascular has compared device materials, design, and performance to the predicate device. Since the subject modifications do not alter the intended use / indications for 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 modified InZone Detachment System to be substantially equivalent to the current legally marketed predicate device cleared in K160096.