March 21, 2025

Stryker Neurovascular
Manmeet Chawla
Senior Project Manager Regulatory Affairs
47900 Bayside Parkway
Fremont, California 94538

Re: K242289
Trade/Device Name: Excelsior XT-27 Microcatheter, Excelsior XT-27 Flex Microcatheter, Excelsior XT-27 Pre-Shaped Microcatheter, Excelsior XT-27 Flex Pre-Shaped Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, KRA
Dated: February 21, 2025
Received: February 21, 2025

Dear Manmeet Chawla:

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,

Naira Muradyan -S

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242289

Device Name
Excelsior XT-27 Microcatheter, Excelsior XT-27 Flex Microcatheter,
Excelsior XT-27 Pre-Shaped Microcatheter, Excelsior XT-27 Flex Pre-Shaped Microcatheter

Indications for Use *(Describe)*

The Excelsior XT-27 Microcatheter and Excelsior XT-27 Flex Microcatheter are intended to assist in the delivery of embolization particles, diagnostic agents (such as contrast media), and interventional devices (such as stents) that are indicated for use in the neurovasculature and with a catheter of 0.027 inches in inner diameter.

The Excelsior XT-27 Pre-Shaped Microcatheter and Excelsior XT-27 Flex Pre-Shaped Microcatheter are intended to assist in the delivery of embolization particles, diagnostic agents (such as contrast media), and interventional devices (such as stents) that are indicated for use in the neurovasculature and with a catheter of 0.027 inches in inner diameter.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K242289

510(k) Summary

Submitter: Stryker Neurovascular
47900 Bayside Parkway
Fremont, CA 94538
Phone: 510-423-2500

Contact: Manmeet Chawla
E-mail: manmeet.chawla@stryker.com

Date Prepared: March 20, 2025

Device Name: Excelsior® XT-27® Microcatheter, Excelsior® XT-27® Flex Microcatheter, Excelsior® XT-27® Pre-Shaped Microcatheter, Excelsior® XT-27® Flex Pre-Shaped Microcatheter

Common Name: Percutaneous catheter

Classification Name: Catheter, Percutaneous, Neurovasculature (21 CFR 870.1250, QJP) and Catheter, Continuous Flush (21 CFR 870.1210, KRA)

Device Classification: Class II

Product Code: QJP and KRA

Predicate Device: Excelsior® XT-27® Microcatheter (K113778, cleared 20-April-2012)

DEVICE DESCRIPTION:

The subject devices hereafter referred to as Excelsior® XT-27® Microcatheters are sterile, single lumen, 0.027 inch inner diameter (ID) microcatheters with one tip marker designed to aid the physician in accessing distal neurovasculature when used with a guide catheter and steerable guidewire. Graded shaft stiffness ranging from a highly flexible tip to a semi-rigid proximal section aids the physician in tracking over selectively placed guidewires. A luer fitting located on the microcatheter hub is used for the attachment of accessories. One radiopaque tip marker is positioned at the distal tip of the device to facilitate fluoroscopic visualization. The Excelsior® XT-27® Microcatheters are coated on the outer surface with Hydrolene™ coating which reduces friction during manipulation in the vessel.

The Excelsior® XT-27® Microcatheters are available in effective lengths of both 135 cm (53.1 inch) and 150 cm (59.1 inch), with two distal shaft configurations achieved through distal shaft lengths of 6 cm (XT-27 model) and 18 cm (XT-27 Flex model). Both straight tip and pre-shaped versions are available. Refer to **Table 1**.

Table 1. Excelsior® XT-27® Microcatheter Types

Product Description	UPN	Effective Length (cm) / Tip Length (cm)
Excelsior® XT-27®, Straight	M003XT2735810	135 / 6
Excelsior® XT-27®, Pre-Shaped	M003XT2735910	135 / 6
Excelsior® XT-27®, Straight	M003XT2750810	150 / 6
Excelsior® XT-27®, Pre-Shaped	M003XT2750910	150 / 6
Excelsior® XT-27®, Flex, Straight	M003XT2735820	135 / 18
Excelsior® XT-27®, Flex, Pre-Shaped	M003XT2735920	135 / 18
Excelsior® XT-27®, Flex, Straight	M003XT2750820	150 / 18
Excelsior® XT-27®, Flex, Pre-Shaped	M003XT2750920	150 / 18

Please note that all Excelsior® XT-27® Microcatheters referenced in this submission are considered the subject device.

The subject Excelsior® XT-27® Microcatheters are a modification to the predicate device, Excelsior® XT-27® Microcatheter (K113778), for the labeling change to recommend the use of the Excelsior® XT-27®Microcatheters with guide catheters with a minimum ID of 0.046 inch (1.17 mm). The technological characteristics and principles of operation remain unchanged except for the use of the Excelsior® XT-27® Microcatheters with guide catheters with a minimum ID of 0.046 inch (1.17 mm). The device design, materials, manufacturing, packaging, and sterilization methods, biocompatibility data, bench-top data, and stability are directly applicable from the predicate device (K113778) and from other changes made since that did not require a 510(k) submission.

Accessories

Each Excelsior® XT-27® Microcatheter is provided with a shaping mandrel and peel away introducer sheath within a separate inner Tyvek™ pouch (accessory pouch) for straight configurations and inside a pre-shaped tray for the pre-shaped configurations. The Excelsior® XT- 27® Microcatheters are available in a single pack (one unit per package) only. The device pouch, Instruction for Use (IFU), and pointer page are provided inside a shelf carton.

INTENDED USE / INDICATIONS FOR USE:

The indications for use are similar between the predicate Excelsior® XT-27® Microcatheter (K113778) and subject Excelsior® XT-27® Microcatheters. Minor modifications for clarity were made to the indications for use (refer to comparison in Table 2). Changes do not impact the intended use of the device.

Indications for Use for Excelsior® XT-27® Microcatheter and Excelsior® XT-27® Flex Microcatheter:

The Excelsior® XT-27® Microcatheter and Excelsior® XT-27® Flex Microcatheter are intended to assist in the delivery of embolization particles, diagnostic agents (such as contrast media), and interventional devices (such as stents) that are indicated for use in the neurovasculature and with a catheter of 0.027 inches in inner diameter.

Indications for Use for Excelsior® XT-27® Pre-Shaped Microcatheter and Excelsior® XT-27® Flex (Pre-Shaped Microcatheter:

The Excelsior® XT-27® Pre-Shaped Microcatheter and Excelsior® XT-27® Flex Pre-Shaped Microcatheter are intended to assist in the delivery of embolization particles, diagnostic agents (such as contrast media), and interventional devices (such as stents) that are indicated for use in the neurovasculature and with a catheter of 0.027 inches in inner diameter.

TECHNOLOGICAL CHARACTERISTICS AND COMPARISON TO THE PREDICATE DEVICE:

Stryker Neurovascular has demonstrated that the subject Excelsior® XT-27® Microcatheters are substantially equivalent to the predicate Excelsior® XT-27® Microcatheter (K113778) based on the same intended use, same or similar materials, similar design, and the same fundamental operating principles.

A comparison of the subject and predicate devices is summarized in **Table 2** below.

Table 2. Comparison of the Subject Devices with the Predicate Device

Characteristic	**Predicate Device** **Excelsior® XT-27® Microcatheter** **(K113778)**	**Subject Device** **Excelsior® XT-27® Microcatheters** **(K242289)**
Manufacturer	Stryker	Same
Device Type	Percutaneous Catheter	Same
Regulation/Class	870.1250, Class II 870.1210, Class II	Same
Product Code	DQY, KRA	QJP, KRA
Intended Use/Indications for Use	The Excelsior XT-27 Microcatheter is intended to assist in the delivery of diagnostic agents (such as contrast media), therapeutic agents, and non-liquid interventional devices (such as stents) that are indicated for use in the neurovasculature and with a catheter of 0.027 inches in inner diameter.	The Excelsior XT-27 Microcatheter and Excelsior XT-27 Flex Microcatheter are intended to assist in the delivery of embolization particles, diagnostic agents (such as contrast media), and interventional devices (such as stents) that are indicated for use in the neurovasculature and with a catheter of 0.027 inches in inner diameter. The Excelsior XT-27 Pre-Shaped Microcatheter and Excelsior XT-27 Flex Pre-Shaped Microcatheter are intended to assist in the delivery of embolization particles, diagnostic agents (such as contrast media), and interventional devices (such as stents) that are indicated for use in the neurovasculature and with a catheter of 0.027 inches in inner diameter.

Characteristic	**Predicate Device** **Excelsior® XT-27® Microcatheter (K113778)**	**Subject Device** **Excelsior® XT-27® Microcatheters (K242289)**
How Supplied	Single use, sterile, non-pyrogenic	Same
Method of Sterilization	Ethylene Oxide (EtO) gas	Same
Materials	PTFE, Pebax, Stainless Steel wire, Nylon, Santoprene	Same
Features		
Tip Configuration	• Straight tip • Pre-Shaped tip *Option for secondary steam shaping by physician prior to use.*	Same
Effective Lengths	135 cm, 150 cm	Same
Proximal OD/ Distal OD	Proximal OD (outer diameter): 2.9F Distal OD: 2.7F	Same
ID	0.027 inch	Same
Hydrophilic Coating Length	80 cm	Same
Tip Length/ Distal Shaft Length	6 cm, 18 cm	Same
Tip Marker	Platinum (90%) / Iridium (10%) alloy	Same
Metal Reinforcement	304 Stainless Steel	Same
Coating	Hydrophilic Polymer	Same

RISK ASSESSMENT:

Risk assessment of the subject modified Excelsior® XT-27® Microcatheters has been conducted in accordance with EN ISO 14971 and Stryker Neurovascular risk management procedures. Stryker Neurovascular has determined that the change in the minimum recommended guide catheter ID as outlined in the compatibility table of the Excelsior® XT-27® Microcatheters IFU raises no new questions of safety or effectiveness. The risk assessment conducted on the subject device did not result in any new hazards or harms.

PERFORMANCE DATA:

Non-clinical tests were performed to demonstrate the subject device performs as intended and substantial equivalence. Bench testing that was performed is summarized in **Table 3**.

Table 3. Bench Testing Summary

Test	Test Method Summary	Results
Guide Catheter Compatibility with 1.17 mm (0.046") ID	A track and Pull Back study was conducted to evaluate the maximum forces required to completely deliver and retrieve an Excelsior® XT-27® Microcatheter inside a 0.046" ID guide catheter with ancillary devices that represent worst-case sizes.	Pass
Tensile Strength for Joints and Marker Band	Tensile strength tested after preconditioning by simulated use with worst-case sized ancillary devices and interventional devices.	Pass
Particulate and Coating Integrity	Hydrophilic coating integrity and particulate generation were evaluated under simulated use conditions with Excelsior® XT-27® Microcatheters used with 0.046" ID guide catheter, with comparison to cleared comparator devices.	Pass

CONCLUSION:

The subject device is substantially equivalent to the predicate device based on similar intended use/indications for use, same or similar materials, same fundamental design, and the same operating principles. The non-clinical testing data support the subject device performs as intended.