



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Stryker Neurovascular
Ms. Yoko Enrile
Principle Regulatory Affairs Specialist
47900 Bayside Parkway
Fremont, CA 94538 US

November 14, 2014

Re: K142565

Trade/Device Name: Excelsior XT-17 Microcatheter, Excelsior XT-17 Flex Microcatheter, Excelsior XT-17 Pre-Shaped Microcatheter, Excelsior XT-17 Flex Pre-Shaped Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheters
Regulatory Class: Class II
Product Code: DQY
Dated: September 11, 2014
Received: September 12, 2014

Dear Ms. Enrile:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Carlos L. Pena -S 

Carlos Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K142565

Device Name

Excelsior XT -17 Microcatheter

Indications for Use (Describe)

Stryker Neurovascular's Excelsior XT -17 Microcatheters are intended to assist in the delivery of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils, into the peripheral, coronary and neuro 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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510(k) Summary

Summary Date November 12, 2014

Submitter Name and Address Stryker Neurovascular
47900 Bayside Parkway
Fremont, CA. 94538

Contact Person: Yoko Y Enrile
Principal Regulatory Affairs Specialist
Phone: 510-413-2619
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Email: yoko.enrile@stryker.com

Trade Name: Excelsior® XT-17™ Microcatheter

Common Name: Percutaneous Catheter; Microcatheter

Classification Name: Percutaneous catheters are currently classified as Class II devices per 21 CFR 870.1250. No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices.

Product Code: DQY

Legally Marketed Predicate Device:

Reference (Clearance Date)	Device
K123452 (3 January 2013)	Tracker-17 Microcatheter

510(k) Summary (cont.)

Device Description and Characteristics:

Stryker Neurovascular **Excelsior® XT-17™ Microcatheters** are single lumen devices designed to aid the physician in accessing distal vasculature 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. A radiopaque tip facilitates fluoroscopic visualization. Stryker Neurovascular hydrophilically coated Excelsior XT-17 Microcatheters are coated on the outer surface with Hydrolene® Coating that reduces friction during manipulation in the vessel.

The Excelsior XT-17 Microcatheter is a single use device made of polymers, stainless steel, and Hydrolene® Coating, sterilized with Ethylene Oxide (EO) gas. Patient contact duration is less than 24 hours, and patient contact materials are polymers and Hydrolene® Coating.

The Excelsior XT-17 Microcatheter is used in health care facility/hospital by physicians trained in performing endovascular procedures.

Accessories:

The Excelsior XT-17 Microcatheter is packaged with an introducer sheath and a steam shaping mandrel accessory.

Indications for Use / Intended Use:

Stryker Neurovascular's Excelsior XT-17 Microcatheters are intended to assist in the delivery of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils, into the peripheral, coronary and neuro vasculature.

Principle of Operations:

The Excelsior XT-17 Microcatheter is used to access and navigate the vasculature as well as to deliver diagnostic and therapeutic agents. The Excelsior XT-17 Microcatheter is inserted with a guide catheter and guided through the vasculature with the aid of a guidewire (over-the-wire microcatheters).

510(k) Summary (cont.)

Technological Characteristics and Product Feature Comparison:

Stryker Neurovascular's Excelsior XT-17 Microcatheter is equivalent to the predicate device in terms of:

- functionality
- method of operation
- intended use
- indication for use
- biological safety

A tabular comparison of the specific technological characteristics between the predicate device and the proposed device is provided below.

510(k) Summary (cont.)

Product feature comparison for the Excelsior® XT-17™ Microcatheter:

Characteristics	Results
Outer Shaft Material (Prox.)	Same as predicate
Outer Shaft Material (Mid)	Same as predicate
Outer Shaft Material (Distal)	Same as predicate
Outer Shaft Material (1.5 cm fluorosaver marker)	Material same as predicate but without colorant
Inner Shaft Material	Same as predicate
Liner	Same as predicate
Hub/Luer	Internal hub dimension for XT-17 is slightly smaller
Shaft Design	<ul style="list-style-type: none">• Offered with a fluorosaver marker• Offered with pre-shaped distal tips
Tip Marker (Proximal)	Same as predicate
Tip Marker (Distal)	Same material, smaller OD
Coating	Same as predicate
Distal Shaft Length	Same as predicate
Mid shaft length	Same as predicate
Mid transition length	Same as predicate
Prox. Shaft Length	Same as predicate
Proximal ID / OD	Same as predicate
Distal ID / OD	Same ID, smaller OD
Effective Length	Same as predicate
Hydrolene Uncoated Length/ Coated length	Same as predicate
Indications for Use	Same as predicate
Sterilization Method	Same as predicate
Packaging Pouch Materials	Offered with Nylon/PE
Packaging Carton	Same as predicate
Packaging Configuration	<ul style="list-style-type: none">• Straight type (Same as Excelsior XT-27 Microcatheter)• Pre-Shaped (Offered with new packaging design)
Accessories	Introducer sheath added
Closure Strip	Same as predicate
DMSO Compatibility	DMSO compatibility information added

Risk assessment of the modifications in the form of design and use failure modes and effects analysis (design and use FMEAs) has been conducted in accordance with EN ISO 14971:2012. Stryker Neurovascular has determined the modifications to the predicate device raise no new questions of safety or effectiveness.

510(k) Summary (cont.)

Performance data: Design verification of the Excelsior XT-17 consisted of:

Functional testing (T=0):

Verification testing to assess:

- Tip Shape Retention
- Tip steam shape shrinkage
- Flexibility of the Distal Shaft
- Softness of the Distal Tip
- Tip shape retention (only applicable to Preshaped catheters)
- Surface defects along effective length
- Surface extraneous matter along effective length
- Static Rupture / Leakage under High Static Pressure
- Dynamic Burst
- Tensile Strength
- Catheter Hub
- Compatibility with DMSO
- Compatibility with Peel-away introducer sheath
- Proximal Fluoro-saver marker visibility

Shelf life testing (Product and Packaging)

Distribution /shipping Challenge Conditioning and Testing

Packaging Verification Testing

Biocompatibility testing:

The biocompatibility evaluation for the proposed Excelsior XT-17 Microcatheter was performed according to EN ISO10993-1:2009 + AC: 2010. The battery of testing comprised the following.

- Cytotoxicity
- Hemolysis
- Physiochemical Test
- FTIR
- Latex

510(k) Summary (cont.)

Conclusion:

The subject modifications do not alter the intended use or indications for use, or the fundamental scientific technology of the predicate device Tracker-17 Microcatheter. The risk assessment of the modifications conducted in accordance with EN ISO 14971: 2012 and successful verification testing demonstrate that the proposed device Excelsior XT-17 Microcatheter was found to have a safety and effectiveness profile that is similar to the predicate device.