

Section 5 510(k) Summary (K122576)

Summary Date: 11 January 2013

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

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Trade Name: TransForm™ Occlusion Balloon Catheter
(Compliant and Super Compliant)

Common Name: Intravascular Occluding Catheter, Temporary

Classification Name: Vascular Clamp (21 CFR 870.4450, Product Code: MJN)

Legally Marketed Predicate Devices: HyperGlide™ and HyperForm™ Occlusion Balloon Systems (K101570), cleared 13 July 2010

Device Description: Stryker Neurovascular's TransForm Occlusion Balloon Catheters (Compliant and Super Compliant) are compliant, variable stiffness reinforced balloon catheters. The outer surface of the catheter's distal segment is coated with a lubricious hydrophilic coating designed to reduce friction. Each balloon catheter has two radiopaque markers to facilitate fluoroscopic visualization. The proximal end of the balloon catheter incorporates a strain relief and a standard luer fitting to facilitate the attachment of accessories.

510(k) Summary Of Safety And Effectiveness (cont.)

Indications for Use / Intended Use:

The Stryker Neurovascular TransForm™ Occlusion Balloon Catheters (Compliant and Super Compliant) are indicated for use in the neuro and peripheral vasculature to temporarily stop or control blood flow and for balloon assisted embolization of intracranial aneurysms.

Accessories:

There are no accessories to the TransForm™ Occlusion Balloon Catheters.

Comparison to Predicate Device:

Intended Use / Indications for Use

Intended Use / Indications for Use are the same as for the predicate device.

Design and Materials

TransForm™ Occlusion Balloon Catheters and predicate ev3 HyperGlide™ and HyperForm™ Occlusion Balloon Systems are similar in design as follows:

- both devices comprise a single lumen catheter with a non-detachable, open-ended balloon attached at the distal end
- both devices are designed to track over a guidewire
- for both devices, inflation of the balloon is accomplished by inserting a guidewire into the distal seal (tip)
- both devices utilize two platinum radiopaque markers to facilitate radiographic visualization
- both catheters utilize a hydrophilic coating to assist in catheter advancement
- both devices are supplied as sterile, single-use devices
- both devices use similar materials (i.e., polymers and metals)

The table on the following page compares the TransForm Occlusion Balloon Catheters to the predicate devices.

510(k) Summary Of Safety And Effectiveness (cont.)

Comparison to Predicate Devices

| Point of Comparison | <p align="center">Predicate ev3 HyperGlide™ and HyperForm™ Occlusion Balloon Systems (K101570)</p> | <p align="center">TransForm™ Occlusion Balloon Catheters (Subject device)</p> |
|---------------------|--|---|
| Intended Use | <p>For use in the blood vessels of the peripheral and neurovasculature where temporary occlusion is desired. These catheters offer a vessel selective technique of temporary vascular occlusion which is useful in selectively stopping or controlling blood flow and for balloon assisted embolization of intracranial aneurysms.</p> | <p>The Stryker Neurovascular TransForm Occlusion Balloon Catheters are indicated for use in the neuro and peripheral vasculature to temporarily stop or control blood flow and for balloon assisted embolization of intracranial aneurysms.</p> |
| Lumen Configuration | Single lumen | Single lumen |
| Effective Length | 150 cm | 150 cm |
| Inner Diameter | 0.010 inch | 0.014 inch |
| Distal OD / Prox OD | Distal: 2.2, 2.5 and 3.0 F Proximal: 2.8 F | Distal: 2.8 F Proximal: 2.8 F |
| Distal Tip Length | 2 mm / 4mm | 3.25 mm |

510(k) Summary Of Safety And Effectiveness (cont.)

Comparison to Predicate Devices (cont.)

| Point of Comparison | Predicate ev3 HyperGlide™ and HyperForm™ Occlusion Balloon Systems (K101570) | TransForm™ Occlusion Balloon Catheters (Subject device) |
|---------------------------|--|--|
| Balloon Diameter / Length | Diameter: 3, 4, 5, 7 mm Length: 7, 10, 15, 20, 30 mm | Diameter: 3, 4, 5, 7 mm Length: 5, 7, 10, 15, 20, 30 mm |
| Materials | Polymers and metals | Polymers and metals |
| Radiopaque Markers | 2 ea. | 2 ea. |
| Coating | Hydrophilic | Hydrophilic |
| Guidewire Compatibility | 0.010 inch | 0.014 inch |
| How supplied | Sterile, single-use | Sterile, single-use |

510(k) Summary Of Safety And Effectiveness (cont.)

Testing and Non-Clinical Performance Data:

Design verification of the TransForm™ Occlusion Balloon Catheters consisted of:

- Functional Testing (bench) to assess:

| | |
|---------------------------------|------------------------------|
| Tip Flexibility | Kink Radius of Curvature |
| Stiffness | Tensile Strength |
| Balloon Compliance | Balloon Shape Retention |
| Max Inflation Volume/Burst Mode | Particulate |
| Balloon Fatigue | Corrosion Resistance |
| Deflation Time | Chemical Compatibility |
| Friction Force | Guide Catheter Compatibility |
| Surface Defects | |

Testing was conducted in accordance with EN ISO 10555-1 and EN ISO 10555-4

- Shelf Life Testing (Product and Packaging)
- Distribution / Shipping Challenge Conditioning and Testing
- Packaging Verification Testing

Assessing the ability of finished packages to withstand the effects of anticipated hazards of the distribution environment on essential packaging characteristics

Assessing the ability of packaging to protect the device and to maintain sterility (sterile barrier testing).

Packaging complies with EN ISO 11607-1 and -2.

- Biocompatibility Testing

Conducted in accordance with EN ISO 10993-1.

Those tests developed specifically for the TransForm Occlusion Balloon Catheter are listed in the table on the following page.

510(k) Summary Of Safety And Effectiveness (cont.)

Tests Developed for the TransForm™ Occlusion Balloon Catheter

| Title | Purpose |
|---|---|
| Rotational Cantilever Stiffness Test Method | To describe the method of testing the flexibility of NEMO and predicate catheter shafts by means of a cantilever bending test. |
| Compliance of Compliant & Super Compliant Balloons and Balloon Nominal Diameter | To measure balloon compliance and balloon nominal diameter on NEMO occlusion balloon catheter. |
| Maximum Inflated Volume / Burst Mode | To measure maximum inflated volume and document the burst mode for NEMO occlusion balloon catheter. |
| Balloon Fatigue | To perform balloon fatigue (multiple inflation/deflation cycles) testing of NEMO occlusion balloon catheter. |
| Deflation Time | To measure deflation time on NEMO occlusion balloon catheter when balloon is deflated from its maximum volume using recommended contrast/saline solution. |
| Occlusion Balloon Catheter Visual Standard | To provide definition of visual defects specified in the Occlusion Balloon Catheter Finished Good drawings. |
| Polyimide Hybrid Catheter Shaft Visual Standard | To provide definition of visual defects specified in the Taper, PI Hybrid Shaft Sub Assy drawings. |
| Balloon Shape Retention | To perform balloon shape retention test on NEMO occlusion balloon catheter. |
| Chemical Pre-Conditioning Procedure | To pre-condition NEMO test units with recommended liquid chemicals prior to conducting chemical compatibility tests as detailed in NEMO occlusion balloon catheters product specification document, 90635788. |
| Occlusion Balloon Wire Movement | To measure the friction force produced as the guidewire tracks through the distal tip seal of the balloon catheter. |
| Balloon Deflation Profile (Peak Pullback Force) | To measure withdrawal force of the deflated balloon through a 5F (0.053") ID guide catheter after 30 balloon inflation/deflation cycles. |
| Product Removal From Hoop | This STM tests to determine if the NEMO Occlusion Balloon Catheter is sufficiently protected by the dispenser hoop during transit and that it will not be kinked or damaged during removal from the hoop. |

510(k) Summary Of Safety And Effectiveness (cont.)

Conclusion:

Based on the comparison information for the indications for use, the technical comparison table above, and the verification/validation testing, the TransForm™ Occlusion Balloon Catheter (Compliant and Super Compliant) was shown to be substantially equivalent to the predicate devices to which equivalence was claimed.



January 11, 2013

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Stryker Neurovascular
c/o Mr. James Leathley
Regulatory Affairs Manager
47900 Bayside Parkway
Fremont, California 94538

Re: K122576

Transform Occlusion Balloon Catheter
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II (Two)
Product Code: MJN (Temporary Intravascular Occluding Catheter)
Dated: December 22, 2012
Received: December 27, 2012

Dear Mr. Leathley:

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 <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 Small Manufacturers, International and Consumer Assistance 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,

Joyce M. Whang

for Victor Krauthamer, Ph.D.
Acting 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): K122576

Device Name: TransForm™ Occlusion Balloon Catheter (Compliant and Super Compliant)

Indications For Use:

The Stryker Neurovascular TransForm Occlusion Balloon Catheters are indicated for use in the neuro and peripheral vasculature to temporarily stop or control blood flow and for balloon assisted embolization of intracranial aneurysms.

Prescription Use x
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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| <p>Joyce M. Whang</p> <p>(Division Sign Off) Division of Neurological and Physical Medicine Devices (DNPMD)</p> <p>510(k) Number <u> K122576 </u></p> |
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