

## 510(K) SUMMARY

APR 28 2010

### 1. Administrative Information

Name: St. Jude Medical  
Address: 14901 DeVeau Place  
Minnetonka, MN 55345  
Phone: 651-756-6522  
Fax: 651-756-3049  
Contact Person: Jennifer Zwiefelhofer  
Senior Regulatory Affairs Specialist  
Date: February 19, 2009

### 2. Device Information

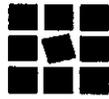
Name of Device: Roll-X™ Interventional Guidewire Portfolio  
Common Name: Guidewire  
Classification Name: Catheter Guidewire (870.1330)  
Product Code: DQX

### 3. Predicate Device Information

Roll-X™ Guidewire (St. Jude Medical) - K082304 cleared Aug 2008  
Asahi Prowater PTCA Coronary Guidewire (Abbott) - K052339 cleared Nov 2005  
Hi-Torque Balance Middleweight Universal (Abbott) - K013833 cleared Jan 2002  
Hi-Torque Balance Heavyweight Guidewire (Abbott) - K982083 cleared Sep 1998

### 4. Device Description

Roll-X™ Guidewires are steerable guidewires constructed of a stainless steel core wire with a coiled wire spring design at the distal end. The core wire is PTFE coated. Roll-X™ Guidewires have a unique distal end design to enhance torque response and control. The distal end of the guidewire is shapeable and is radiopaque. The guidewires are provided sterile and non-pyrogenic.



## **5. Intended Use**

Roll-X Guidewires are intended to facilitate the placement of balloon dilation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The wires are also intended to facilitate the placement of compatible interventional devices during therapeutic intravascular procedures. The guidewires are not to be used in cerebral blood vessels.

## **6. Technological Characteristics**

The Roll-X Guidewires as compared to the Roll-X, Asahi Prowater, Hi-Torque BMW and Hi-Torque BHW guidewires are substantially equivalent in many ways, including intended use, design, material types, and technology as outlined below.

### **Intended Use:**

- Roll-X, Prowater, BMW and BHW guidewires have the same intended indication which is to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The wire is also intended to facilitate the placement of compatible interventional devices during therapeutic intravascular procedures.

### **Product Design, Material Types and Technology:**

- Sized 0.014"
- Available in similar lengths (180, 185 or 190cm and 300 cm)
- Contain a SST core wire
- Contain a distal radiopaque coil
- Have flexible tip designs that can be shaped by the user
- Are joined by a combination of solders, welds, and/or adhesives
- Proximal SST cores wires are PTFE coated
- Contain a hydrophilic coating on the distal end

## **7. Summary of Non-clinical Testing**

Performance testing of the Roll-X Guidewires consists of bench and animal testing. Results of the testing demonstrate that the guidewire design meets product specifications and intended uses. A summary of the bench and performance testing conducted is listed below:

### Performance Testing Summary

Item	Tests
Device performance	<ul style="list-style-type: none"> <li>• Tensile Strength</li> <li>• Torque Strength</li> <li>• Torqueability</li> <li>• Tip Flexibility</li> <li>• Catheter Compatibility</li> <li>• Coating Adherence/Integrity</li> <li>• Flexing Test</li> <li>• Fracture Test</li> <li>• Corrosion Resistance</li> <li>• Radiopacity</li> <li>• Steering Response</li> <li>• Tip Load Test</li> </ul>
Biocompatibility	<ul style="list-style-type: none"> <li>• Cytotoxicity</li> <li>• Sensitization</li> <li>• Irritation</li> <li>• Acute Systemic Toxicity</li> <li>• Hemolysis</li> <li>• Partial Thromboplastin Time</li> <li>• Complement Activation</li> <li>• In vivo Thromboresistance</li> </ul>
Sterilization/Microbiology	<ul style="list-style-type: none"> <li>• Ethylene Oxide Sterilization Evaluation</li> <li>• Bioburden</li> <li>• EO residuals</li> <li>• Endotoxin</li> </ul>
Packaging	<ul style="list-style-type: none"> <li>• Pouch Peel Test</li> <li>• Visual Inspection</li> <li>• Pouch Seal Integrity</li> </ul>
Shelf Life	<ul style="list-style-type: none"> <li>• Same as device performance and packaging</li> </ul>
Animal Testing	<ul style="list-style-type: none"> <li>• Study #1 – assess performance as compared to currently marketed guidewire</li> <li>• Study #2 – development of hydrophilic coating scheme</li> </ul>

## 8. Substantial Equivalence Conclusion

The Roll-X™ Guidewires described in this 510(k) are substantially equivalent to the St. Jude Medical Roll-X™ Guidewire (K082304), the Abbott Vascular ASAHI Prowater Coronary Guidewire (K052339), the Abbot Vascular (previously Guidant Vascular Intervention) Hi-Torque Balance Middleweight™ Universal Guidewire (K013833) and the Abbot Vascular (previously Guidant Vascular Intervention) Hi-Torque® Balance Heavy Weight Guidewire (K982083). The intended use, design, material types, technology, and performance of the Roll-X™ Guidewires are equivalent to the predicate devices. There are no differences between devices which would raise issues of safety or effectiveness.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room W-O66-0609  
Silver Spring, MD 20993-0002

St. Jude Medical  
c/o Mr. Mark Job  
Responsible Third Party Official  
Regulatory Technologies Services LLC  
1394 25<sup>th</sup> Street NW  
Buffalo, MN 55313

APR 28 2010

Re: K100710  
Trade/Device Name: Roll-X™ Interventional Guidewire Portfolio  
Regulation Number: 21 CFR 870.1330  
Regulation Name: Catheter Guidewire  
Regulatory Class: Class II (two)  
Product Code: DQX  
Dated: March 11, 2010  
Received: March 12, 2010

Dear Mr. Job:

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.

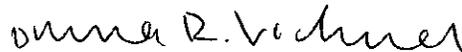
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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/CDRHOices/ucm115809.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" (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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



 Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K100710

Device Name: Roll-X™ Interventional Guidewire Portfolio

### Indications For Use:

Roll-X Guidewires are intended to facilitate the placement of balloon dilation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The wires are also intended to facilitate the placement of compatible interventional devices during therapeutic intravascular procedures. The guidewires are not to be used in cerebral blood vessels.

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Diana R. Vachner*  
(Division Sign-Off)  
Division of Cardiovascular Devices

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