



## 510(K) SUMMARY

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### 1. ADMINISTRATIVE INFORMATION

Name: St. Jude Medical  
Address: 14901 DeVeau Place  
Minnetonka, MN 55345  
Phone: 763-383-2640  
Fax: 763-383-2556  
Contact Person: Jeff Sturm  
Principal Regulatory Affairs Specialist  
Date: August 6, 2008

### 2. DEVICE INFORMATION

Name of Device: Roll-X™ Guidewire  
Common Name: Coronary Guidewire  
Classification Name: Catheter Guide Wire (870.1330)  
Product Code: DQX

### 3. PREDICATE DEVICE INFORMATION

Asahi Prowater PTCA Coronary Guidewire (Abbott)- K052339 cleared Nov 2005  
Hi-Torque Balanced Middleweight Universal (Abbott)- K013833 cleared Jan 2002

### 4. DEVICE DESCRIPTION

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

### 5. INTENDED USE

The Roll-X Guidewire is intended 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 stent devices during therapeutic intravascular procedures. The guidewire is not to be used in the cerebral blood vessels.



**ST. JUDE MEDICAL**

MORE CONTROL. LESS RISK.

## 6. TECHNOLOGICAL CHARACTERISTICS

Comparisons of the new and predicate devices show that the technological characteristics such as product performance, design and intended use are substantially equivalent to the currently marketed predicate devices.

## 7. SUMMARY OF NON-CLINICAL TESTING

Non-clinical testing of the Roll-X™ Guidewire includes in vitro bench testing, animal evaluation, biocompatibility testing, shelf-life and package testing and sterilization evaluation. Results of the testing demonstrate that the guidewire design meets product specifications and intended uses.

## 8. SUBSTANTIAL EQUIVALENCE CONCLUSION

The Roll-X™ Guidewire described in this 510(k) is substantially equivalent to the ASAHI Prowater PTCA Coronary Guidewire (K052339) and Hi-Torque Balanced Middleweight Universal Guidewire (K013833). The intended use, design, material types, technology, and performance of the Roll-X™ Guidewire is equivalent to the predicate devices. There are no differences between devices which would raise issues of safety or effectiveness.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 27 2008

St. Jude Medical  
c/o Mr. Jeff Sturm  
Principal Regulatory Affairs Specialist  
14901 DeVeau Place  
Minnetonka, MN 55345

Re: K082304  
Trade/Device Name: Roll-X™ Coronary Guidewire  
Regulation Number: 21 CFR 870.1330  
Regulation Name: Catheter Guide Wire  
Regulatory Class: Class II  
Product Code: DQX  
Dated: August 12, 2008  
Received: August 13, 2008

Dear Mr. Sturm:

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 such 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); good manufacturing practice requirements as set forth in the quality

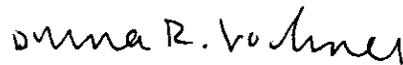
Page 2 – Mr. Jeff Sturm

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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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/cdrh/industry/support/index.html>.

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): K082304

Device Name: Roll-X™ Coronary Guidewire

### Indications for Use:

Roll-X Coronary Guidewires are intended 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 stent devices during therapeutic intravascular procedures. The Guidewire is not to be used in the 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)

*Donna R. Volmer*  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number K082304