9.0 510(K) SUMMARY

K083146

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

NOV 21 2008

APPLICANT
Asahi Intecc Co., Ltd.
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Nagoya, Aichi 463-0024
Japan

OFFICIAL CORRESPONDENT
Yoshi Terai
President, CEO
Asahi Intecc USA, Inc.
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TRADE NAME: Asahi Regalia XS 1.0 Peripheral Guide Wire

COMMON NAME: Guide Wire

CLASSIFICATION NAME: Wire, Guide, Catheter

DEVICE CLASSIFICATION: Class 2 per 21 CFR §870.1330

PRODUCT CODE DQX

PREDICATE DEVICE: Asahi PTCA Guide Wire Fielder – K052022
Asahi Treasure Guide Wire – K061984

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Asahi Regalia XS 1.0 Peripheral Guide Wire is steerable guide wire with a maximum diameter of 0.014 inches (0.36mm) and available in 180 cm and 300 cm length. The extension wire is connected to the end of the guide wire outside the body. The wire is constructed from a stainless steel core wire. The core wire and coil are soldered. The distal tip of the guide wire has a radiopaque tip to achieve visibility, and is made flexible to bend easily at the vessel curve. There is polyurethane coating covered with hydrophilic coating applied to the distal section of the guide wire. The proximal section of this guide wire is coated with PTFE.

INDICATION FOR USE:

The Asahi Regalia XS 1.0 Peripheral Guide Wire is intended to facilitate the placement and exchange of diagnostic and therapeutic devices during intravascular procedures. This device is intended for peripheral vascular use only.

TECHNICAL CHARACTERISTICS:

The Asahi Regalia XS 1.0 Peripheral Guide Wire is made of the same materials that have been used in other predicate devices that are labeled for the similar indications. The dimensional specifications are equivalent to those listed for the currently cleared predicate devices.

PERFORMANCE DATA:

This submission represents a change to the existing product labeling. Additional performance testing is not applicable.

SUMMARY/CONCLUSION:

The Asahi Regalia XS 1.0 Peripheral Guide Wire characteristics are substantially equivalent to the specified predicate devices and other currently marketed devices for the same indication for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2008

Asahi Intecc Co., Ltd.
c/o Mr. Yoshi Terai
2500 Red Hill Avenue, Suite 210
Santa Ana, CA 92705

Re: K083146
Trade/Device Name: Asahi Regalia XS 1.0 Peripheral Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guidewire
Regulatory Class: Class II
Product Code: DQX
Dated: October 2, 2008
Received: October 23, 2008

Dear Mr. Terai:

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 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 Biometric's (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,

Donna R. Bachner

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

Enclosure

2.0 INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K083146

Device Name: Asahi Regalia XS 1.0 Peripheral Guide Wire

Indications for Use:

The Asahi Regalia XS 1.0 Peripheral Guide Wire is intended to facilitate the placement and exchange of diagnostic and therapeutic devices during intravascular procedures. This device is intended for peripheral vascular use only.

Prescription Use X AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Ve Ames

(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K083146