9.0 510(K) SUMMARY

K072431

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

SEP 26 2007

APPLICANT	Asahi Intecc Co., Ltd. 1703 Wakita-cho, Moriyama-ku Nagoya, Aichi 463-0024 Japan
OFFICIAL CORRESPONDENT	Yoshi Terai President, CEO Asahi Intecc USA, Inc. 2500 Red Hill Avenue, Suite 210 Santa Ana, CA 92705 Tel: (949) 756-8252 FAX (949) 756-8165 e-mail: yoshi@asahi-intecc.com
TRADE NAME:	Asahi PTCA Guide Wire, X-treme
COMMON NAME:	Guide Wire
CLASSIFICATION NAME:	Catheter Guide Wire
DEVICE CLASSIFICATION:	Class 2 per 21 CFR §870.1330
PRODUCT CODE	DQX
PRIMARY PREDICATE DEVICE:	Asahi PTCA Guide Wire, Fielder – K052022 Asahi PTCA Guide Wire, Fielder FC– K063819

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Asahi PTCA Guide Wire, X-treme is a steerable guide wire with a maximum diameter of 0.014 inches (0.36mm) and available in 190 cm and 300 cm length. The extension wire is connected to the end of the guide wire outside the body for 190cm wire. 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 of soft to easy bend with the vessel curve, and is available with a straight tip. There is polyurethane coating covered with hydrophilic coating applied to the distal section of the guide wire and dimethylpolysiloxane (silicone oil – not contacting blood) is applied to gape space in spring-coil in the tip part. The proximal section of this guide wire is coated with PTFE.

INDICATION FOR USE:

The ASAHI PTCA Guide Wire, X-treme is intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The Asahi PTCA Guide Wires are not to be used in the cerebral blood vessel.

TECHNICAL CHARACTERISTICS:

The ASAHI PTCA Guide Wire, X-treme is of the same materials as the predicate devices. The dimensional specifications and design of the device ensures compatibility for the intended use.

PERFORMANCE DATA:

This 510(k) notice includes mechanical and functional bench testing that demonstrates that the ASAHI PTCA Guide Wire, X-treme performs as intended.

SUMMARY/CONCLUSION:

The ASAHI PTCA Guide Wire, X-treme characteristics are substantially equivalent to the specified predicate devices and other currently marketed devices for the same indication for use.

Bench testing demonstrates that the device functions as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 26 2007

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

Re: K072431
Asahi PTCA Guide Wire, X-treme
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II (two)
Product Code: DQX
Dated: August 21, 2007
Received: August 29, 2007

Dear Mr. Terai:

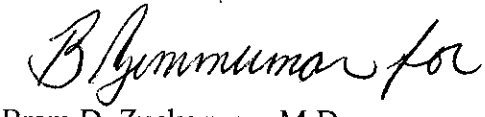
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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

2.0 INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K072431

Device Name: ASAHI PTCA Guide Wire, X-treme

Indications for Use:

The ASAHI PTCA Guide Wire, X-treme is intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The Asahi PTCA Guide Wires are not to be used in the cerebral blood vessel.

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)

B Chaudhuri

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K072431