K101985

9.0 510(K) SUMMARY

MAR - 7 2011

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.

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.terai@asahi-intecc.com

TRADE NAME:	Asahi Guide Wire Extension 165cm
COMMON NAME:	Guide Wire Extension
CLASSIFICATION NAME:	Wire, Guide, Catheter
DEVICE CLASSIFICATION:	Class 2 per 21 CFR §870.1330
PRODUCT CODE	DQX
PREDICATE DEVICE:	Asahi Guide Wire Extension - 510(k) K083145

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Asahi Guide Wire Extension (Asahi Extension Wire) accessory is used to elongate the working length of compatible Asahi PTCA and Peripheral extendable wires. The stainless-steel Asahi Guide Wire Extension (Asahi Extension Wire) has an outer diameter of 0.014" (0.36mm) and a length of 165cm. Its distal end bears a preformed elastic connecting tube. The product is specially designed to use with Asahi PTCA and Peripheral extendable guide wires. This product is a non-invasive medical device, and it is not contact with tissue and body fluids.

INDICATION FOR USE:

The Asahi Guide Wire Extension accessory is intended for extension of the working length of an already introduced guide wire when exchanging over-the-wire interventional devices during an angioplasty procedure.

TECHNICAL CHARACTERISTICS:

The *Guide Wire Extension accessory* is made of the same materials that have been used in other predicate device that is labeled for the same indication. This submission represents minor dimensional specification changes in length. All other specifications are equivalent to those listed for the currently cleared predicate devices.

PERFORMANCE DATA:

Enclosed within this submission is performance data that demonstrates that the Asahi Guide Wire Extension accessory meets all predetermined performance criteria.

In vitro bench testing including bench performance evaluation for Joint strength of Extension Wire and PTCA Guide Wire, Joint strength for extension tube and core wire and Kink test/evaluation of Extension wire with the predicate device as listed below were conducted on the subject device - Asahi Guide Wire Extension accessory/Asahi Guide Wire Extension 165cm. This 510(k) notice includes mechanical and functional bench testing that demonstrates that the Asahi Guide Wire Extension accessory performs as intended.

Performance test/evaluation summary:

1. Bench performance evaluation for joint part strength of Extension Wire 165cm (Joint strength test of extension wire 165cm and PTCA Guide Wire)
2. Bench performance evaluation for tensile strength of Extension Wire 165cm (Joint strength test for extension tube and core wire of Extension Wire)
3. Kink test/evaluation report for Extension wire 165cm with the predicate device

SUMMARY/CONCLUSION:

The Asahi Guide Wire Extension accessory characteristics are substantially equivalent to the specified predicate device and other currently marketed devices for the same indication for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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

Re: K101985
Trade Name: Asahi Guide Wire Extension 165 cm
Regulation Number: 21 CFR 870.1330
Regulation Name: Wire, Guide, Catheter
Regulatory Class: Class II
Product Code: DQX
Dated: January 20, 2011
Received: January 21, 2011

MAR - 7 2011

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. 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

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/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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Donna R. Lochner

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): K101985

Device Name: Asahi Guide Wire Extension 165cm

Indications for Use:

The Asahi Guide Wire Extension accessory is intended for extension of the working length of an already introduced guide wire when exchanging over-the-wire interventional devices during an angioplasty procedure.

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. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101985