K091188

9.0 510(K) SUMMARY

FEB 2 6 2010

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 ZenyteEX Guiding Catheter
COMMON NAME:	Guide Catheter
CLASSIFICATION NAME:	Catheter, Percutaneous
DEVICE CLASSIFICATION:	Class 2 per 21 CFR §870.1250
PRODUCT CODE	DQY
PREDICATE DEVICE:	K023402 & K022764 – Medtronic Launcher Guide Catheter K972484 - ACS Viking Guiding Catheter K061601 - Precious Guide Catheter K020028 - Mach 1 Guide Catheter

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The ASAHI ZenyteEX Guiding Catheter is intended for use in coronary or peripheral vascular applications and is designed to provide a pathway through which medical instruments, such as balloon catheters, guide wires or other therapeutic devices may be introduced. The Catheter consists of a tube, which is to be inserted into vasculature, a proximal hub/connector, and strain relief/protector for the joint portion of the first 2 sections. The tube body section consists of soft tip, soft tube and shaft. The tube body itself is constructed of a polyamide elastomer. The shaft is reinforced by stainless steel braid, and it consists of two layers. The distal portion of the tube is made soft in order to easily bend.

INDICATION FOR USE:

ASAHI ZenyteEX Guiding Catheter is intended for use in coronary or peripheral vascular applications and is designed to provide a pathway through which medical instruments, such as balloon catheters, guide wires or other therapeutic devices may be introduced. This device is not intended for use in the cerebral vasculature.

TECHNICAL CHARACTERISTICS:

The ASAHI ZenyteEX Guiding Catheter 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:

All components that come in direct contact with the patient have a long history of use in medical devices and are proven to be biocompatible for use in the vasculature. Furthermore, this submission contains biocompatibility testing conducted on the subject device. This 510(k) notice also includes mechanical and functional bench testing that demonstrates that the ASAHI ZenyteEX Guiding Catheter performs as intended.

SUMMARY/CONCLUSION:

The ASAHI ZenyteEX Guiding Catheter 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
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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

FEB 2 6 2010

Re: K091188
Trade/Device Name: ASAHI ZenyteEX Guiding Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: January 20, 2010
Received: January 27, 2010

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 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/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 (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

2.0 INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K091188

Device Name: ASAHI ZenyteEX Guiding Catheter

Indications for Use:

ASAHI ZenyteEX Guiding Catheter is intended for use in coronary or peripheral vascular applications and is designed to provide a pathway through which medical instruments, such as balloon catheters, guide wires or other therapeutic devices may be introduced. This device is not intended for use in the cerebral vasculature.

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)

Susan D. Richardson

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K091188