9.0 510(K) SUMMARY

K083127

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@asahi-intecc.com
TRADE NAME:	Asahi Corsair Microcatheter
COMMON NAME:	Microcatheter
CLASSIFICATION NAME:	Percutaneous Catheter
DEVICE CLASSIFICATION:	Class 2 per 21 CFR §870.1250
PRODUCT CODE	DQy
PREDICATE DEVICE:	Asahi Stride Microcatheter – K062885 Asahi Tornus Catheter – K051772 Boston Scientific – Tracker Excel – 14 pre-shaped Microcatheter – K050599

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The ASAHI Corsair Microcatheter consists of distal tip and a shaft tube that are inserted into a vascular connector for catheter control and infusion of contrast media. The Corsair has a radiopaque marker coil is imbedded into the inner layer of resin to facilitate the tip location during angiographic procedures. In addition, the device is coated with sodium hyaluronate on the outer surface of shaft tube to provide a smooth transition in blood vessel. The Distal tip of the Corsair has a tapered shape and is designed to have increased flexiblility towards distal side. PTFE is applied to the inner lumen of Catheter for the purpose of smooth transition and exchange of guidewire. The Microcatheter also reinforcement wires that are knitted between hypoblast and intercellular layer to reinforce the distal tip and shaft tube to allow the physician greater control of the device during interventional procedures.

9. 510(K) SUMMARY

INDICATION FOR USE:

The Asahi Corsair Microcatheter is intended to provide support to facilitate the placement of Guide wires in the coronary and peripheral vasculatures and can be used to exchange one guide wire for another. The Corsair Microcatheter is also intended to assist in the delivery of contrast media into the coronary, peripheral and abdominal vasculatures.

TECHNICAL CHARACTERISTICS:

The Asahi Corsair Microcatheter 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 Corsair Microcatheter performs as intended.

SUMMARY/CONCLUSION:

The Asahi Corsair Microcatheter 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

FEB - 3 2009

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

Re: K083127
Trade/Device Name: Asahi Corsair Microcatheter
Common Name: Percutaneous Catheter
Regulation Number: 21 CFR 870.1250
Regulatory Class: II
Product Code: DQY
Dated: January 22, 2008
Received: January 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) 276-0210. 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,

Donna R. Vickner

for 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): K083127

Device Name: Asahi Corsair Microcatheter

Indications for Use:

The Asahi Corsair Microcatheter is intended to provide support to facilitate the placement of Guide wires in the coronary and peripheral vasculatures and can be used to exchange one guide wire for another. The Corsair Microcatheter is also intended to assist in the delivery of contrast media into the coronary, peripheral and abdominal vasculatures.

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. Vechner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K083127