K051792

9.0 SUMMARY OF SAFETY AND EFFECTIVENESS

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. 1301 Dove Street, Suite 350 Newport Beach, CA 92660 Tel: (949) 756-8252 FAX (949) 756-8165 e-mail: yoshi@asahi-intecc.com
TRADE NAME:	Tornus Support Catheter
COMMON NAME:	Guide Catheter
CLASSIFICATION NAME:	Percutaneous Catheter
DEVICE CLASSIFICATION:	Class 2 per 21 CFR §870.1250
PRODUCT CODE	DQY
PREDICATE DEVICE:	XTRAK Support Catheter (K032660) ILT Support Catheter (K012169)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The ASAHI Tornus support catheter is a device that is intended to provide additional support to a steerable guidewire when accessing discrete regions of the coronary and peripheral vasculature. The Tornus Catheter contains a full metal spiral shaft that provides enhanced pushability when attempting to cross difficult lesions. The full metal shaft provides the user with a device that has exclient torqability and pushability during intravascular procedures.

INDICATION FOR USE:

The ASAHI Tornus support catheter is intended to be used in conjunction with a steerable guidewire to access discrete regions of the vasculature and for guidewire exchange.

TECHNICAL CHARACTERISTICS:

The Asahi Tornus support catheter is made of the same materials that have been used in other Asahi products that are labeled for use in the vasculature. The dimensional specifications and the guidewire use compatibility specifications are the 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. This 510(k) notice includes mechanical and functional bench testing that demonstrates that the ASAHI Tornus support catheter performs as intended.

SUMMARY/CONCLUSION:

The ASAHI Tornus support catheteristics 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 2005

Asahi Intecc USA, Inc.
c/o Mr. Yoshi Terai
President, CEO
1301 Dove Street, Suite 350
Newport Beach, CA 92660

Re: K051772
Tornus Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: II
Product Code: DQY
Dated: September 14, 2005
Received: September 14, 2005

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vuchinich

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): K051772

Device Name: ASAHI Tornus Support Catheter

Indications for Use:

The ASAHI Tornus support catheter is intended to be used in conjunction with a steerable guidewire to access discrete regions of the vasculature and for guidewire exchange.

Prescription Use ✓ 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. Vuchnes

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K051772

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