K051561

NOV - 2 2005

510(k) Summary of Safety and Effectiveness

Date Prepared:	June, 2005
Submitted:	Asahi Intecc Co., Ltd. 1703 Wakita-cho, Moriyama-ku, Nagoya, Aichi, 463-0024, Japan.
Contact Person:	Yoshi Terai Director of Asahi Intecc USA Inc.
Address:	1301 Dove Street, Suite #350 Newport Beach, CA, 92660, USA
Phone Number:	Phone: (949) 756-8252
Fax Number:	Fax: (949) 756-8165
Device Trade Name:	Asahi Angiographic Catheter
Classification Name:	Diagnostic intravascular catheter (per 21 CFR 870.1200)
Classification:	Class II
Predicate Device:	K960975: 4F Infiniti Angiographic Catheter K970854: 5F and 6F Infiniti Angiographic Catheter K862006: Stand & High Flow Femoral- Ventricular Pigtail Catheter

Device Description:

The Asahi Angiographic Catheter consists, as its basic structure, of a tube to be inserted into vascular, a proximal hub, and strain relief for the joint section of the first 2 parts. The tube is reinforced by stainless steel braid. The distal tip of the catheter is made soft and has variety configuration in order to easily bend in accordance with the vessel curve. The tube is radiopaque in whole length so as to be easily confirmed its position under radioscopy.

Intended Use:

The Asahi Angiographic Catheters are indicated for the delivery of radiopaque contrast medium to selected sites in the vascular system.

Device Technological Characteristics and Comparison to Predicate Device:

The Asahi Angiographic Catheters are made of the same materials, available in the same diameters and lengths, have the same design and indications for use as the predicate devices and other currently marketed angiographic catheters.

Performance Data:

Bench and biocompatibility testing were conducted according to the relevant ISO to demonstrate that the Asahi Angiographic Catheter met the acceptance criteria and performed similarly to the predicate devices.

All direct and indirect blood contact materials used to fabricate the Asahi Angiographic Catheters pass the testing required by ISO-10993 series. These materials are currently used in many disposable medical devices.

Conclusion:

The Asahi Angiographic Catheters are substantially equivalent to the claimed predicates devices and other currently marketed angiographic catheters.

K051561

Premarket Notification [510(k)] Number

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 2 2005

Asahi Intec Co., Ltd.
c/o Mr. Yoghi Terai
Director
1301 Dove Street, #350
Newport Beach, CA 92660

Re: K051561
Asahi Angiographic Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: II
Product Code: DQO
Dated: September 27, 2006
Received: September 27, 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051561

Device Name: Asahi Angiographic Catheter

Indications For Use:
The Asahi Angiographic Catheters are indicated for the delivery of radiopaque contrast medium to selected sites in the vascular system.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vichney

(Division Sign-Off)
Division of Cardiovascular Devices

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