JUN 13 2007

K062885

9.0 510(K) SUMMARY

This 510(k) summary 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:	Stride Microcatheter
COMMON NAME:	Microcatheter
CLASSIFICATION NAME:	Percutaneous Catheter
DEVICE CLASSIFICATION:	Class 2 per 21 CFR §870.1250
PRODUCT CODE	DQY
PREDICATE DEVICE:	Boston Scientific Tracker Excel - 14 (K050599) Cordis Transit/Rapid Transit/Spedster/Prowler (K972518) ASHAI Tornus Support Catheter (K051772)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

Asahi Stride Microcatheter consists of catheter (soft tip tube and shaft tube), protector tube, strain relief, hub connector, and radiopaque marker in the soft tip tube. The proximal shaft is reinforced with a stainless steel braid wire to enhance pushability. The device is provided in a 2.2 Fr size with lengths ranging from 105 cm to 150 cm. The device also comes with both straight and angled tips.

INDICATION FOR USE:

The ASAHI Stride Microcatheter is intended to provide support to facilitate the placement of guide wires in the coronary and peripheral vasculature and can be used to exchange one guidewire for another. The Asahi Stride Microcatheter is also intended to assist in the delivery of diagnostic agents, such as contrast media and therapeutic agents, such as occlusion coils into the coronary and peripheral vasculature.

TECHNICAL CHARACTERISTICS:

The ASAHI Stride 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 Stride Microcatheter performs as intended.

SUMMARY/CONCLUSION:

The ASAHI Stride Microcatheter 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
9200 Corporate Boulevard
Rockville MD 20850

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

JUN 1 8 2007

Re: K062885
Stride Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: II (two)
Product Code: DQY
Dated: March 20, 2007
Received: March 30, 2007

Dear Mr. Terai:

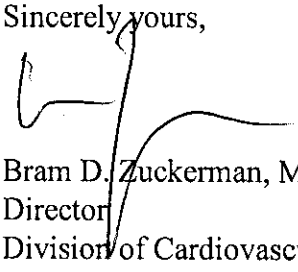
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (240) 276-3150 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

2.0 INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K062885

Device Name: Stride Microcatheter

Indications for Use:

The ASAHI Stride Microcatheter is intended to provide support to facilitate the placement of guide wires in the coronary and peripheral vasculature and can be used to exchange one guidewire for another. The Asahi Stride Microcatheter is also intended to assist in the delivery of diagnostic agents, such as contrast media and therapeutic agents, such as occlusion coils into the coronary and peripheral 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)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K062885

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