

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.

OCT - 5 2006

APPLICANT Asahi Intecc Co., Ltd.
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Japan

**OFFICIAL
CORRESPONDENT** Yoshi Terai
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TRADE NAME: Treasure

COMMON NAME: Guide Wire

**CLASSIFICATION
NAME:** Catheter Guide Wire

**DEVICE
CLASSIFICATION:** Class 2 per 21 CFR §870.1330

PRODUCT CODE DQX

PREDICATE DEVICE: Boston Scientific V-18 guide wire (K033724)
HI-Torque Steelcore 18 guide wire (K982876)
JOMED JoWire (K022762)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Asahi Treasure peripheral guide wire is a steerable guide wire with a diameter of 0.018" and available in 180 cm and 300 cm lengths. The extension wire is connected to the end of the guide wire outside the body for 180 cm wire. The wire is constructed from a stainless steel core wire with spring. The core wire and coil are soldered together. The distal end of the guide wire has a radiopaque tip that is straight and is soft to easily bend with the vessel curve. The hydrophilic coating is applied to the distal portion of the guide wire. The proximal section of the guide wire is coated with PTFE.

INDICATION FOR USE:

The ASAHI Treasure guide wire is intended to facilitate the placement and exchange of diagnostic and therapeutic devices during intravascular procedures. This device is intended for peripheral vascular use only.

TECHNICAL CHARACTERISTICS:

The ASAHI Treasure guide wire 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 reference to a predicate ASAHI devices that uses the same materials as used in the subject device. This 510(k) notice includes mechanical and functional bench testing that demonstrates that the ASAHI Treasure guide wire performs as intended.

SUMMARY/CONCLUSION:

The ASAHI Treasure guide wire 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

OCT - 5 2006

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

Re: K061984
Treasure Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: September 20, 2006
Received: September 26, 2006

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.

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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.

INDICATIONS FOR USE STATEMENT

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510(k) Number (if known): K061984

Device Name: Treasure

Indications for Use:

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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)

Anna R. Kochner
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K061984

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