



Food and Drug Administration  
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April 7, 2016

ASAHI Intecc Co., Ltd.  
% Ms. Candace Cederman  
Senior Regulatory Affairs Consultant  
CardioMed Device Consultants, LLC  
5523 Research Park Drive, Suite 205  
Baltimore, Maryland 21228

Re: K160659

Trade/Device Name: ASAHI CHIKAI Neurovascular Guide Wire  
Regulation Number: 21 CFR 870.1330  
Regulation Name: Catheter Guide Wire  
Regulatory Class: Class II  
Product Code: MOF  
Dated: March 7, 2016  
Received: March 8, 2016

Dear Ms. Candace Cederman:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Carlos L. Peña 

Carlos L. Peña, PhD, MS  
Director  
Division of Neurological  
and Physical Medicine Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K160659

Device Name

ASAHI CHIKAI Neurovascular Guide Wire

Indications for Use (Describe)

ASAHI CHIKAI Neurovascular Guide Wire is intended to be used in the neuro vasculature to facilitate the placement and exchange of therapeutic devices such as cerebral catheters during intravascular therapy. This guide wire is intended for use only in the neuro vasculature.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Special 510(k) Premarket Notification  
ASAHI Neurovascular Guide Wire: ASAHI CHIKAI Round Curve

**510(k) Summary**  
(as required by 21 CFR 807.92)



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**ASAHI Neurovascular Guide Wire: ASAHI CHIKAI Round Curve**

**510(k) [K160659]**

<b>DATE PREPARED:</b>	March 7, 2016
<b>APPLICANT</b>	ASAHI Intecc Co., Ltd. 1703 Wakita-cho, Moriyama-ku Nagoya, Aichi 463-0024, Japan
<b>OFFICIAL CORRESPONDENT</b>	Carroll Councilman Sr. RA Manager ASAHI Intecc USA, Inc. 2500 Red Hill Avenue, Suite 210 Santa Ana, CA 92705 Tel: (949) 756-8252 FAX: (949) 756-8165 e-mail: <a href="mailto:ASAHI.ra-fda@ASAHI-intecc.com">ASAHI.ra-fda@ASAHI-intecc.com</a>
<b>TRADE NAME:</b>	ASAHI CHIKAI Neurovascular Guide Wire
<b>DEVICE CLASSIFICATION:</b>	Class 2 per 21 CFR §870.1330
<b>CLASSIFICATION NAME:</b>	Wire, Guide, Catheter, Neurovasculature
<b>PRODUCT CODE</b>	MOF- Catheter Guide Wire
<b>PREDICATE DEVICES:</b>	ASAHI CHIKAI Neurovascular Guide Wire (K110584)

**INTENDED USE/INDICATIONS FOR USE**

ASAHI CHIKAI Neurovascular Guide Wire is intended to be used in the neuro vasculature to facilitate the placement and exchange of therapeutic devices such as cerebral catheters during intravascular therapy. This guide wire is intended for use only in the neuro vasculature.

**DEVICE DESCRIPTION:**

The ASAHI CHIKAI Neurovascular Guide Wire (Round Curve) is a steerable guide wire with a maximum diameter of 0.014 inches (0.36mm) and available in 200 cm and 300 cm lengths. The guide wire is constructed from a stainless steel core wire with platinum-nickel and stainless steel coils. The coil assembly consists of an inner coil and an outer coil, and the coil

Special 510(k) Premarket Notification  
 ASAHI Neurovascular Guide Wire: ASAHI CHIKAI Round Curve

assembly is soldered to the core wire. The coil assembly construction is identical to the 510(k) cleared ASAHI CHIKAI Neurovascular Guide Wire (K110584).

The distal end of the guide wire has a radiopaque tip to achieve visibility. This change introduces a rounded tip configuration designed to bend with the vessel curve. A hydrophilic coating is applied to the distal portion of the guide wire. The proximal section of the guide wire for 300 cm wire is coated with PTFE.

**COMPARISON WITH PREDICATE DEVICES:**

Comparisons of the CHIKAI Round Curve to its predicate device show that the technological characteristics of the Subject device such as the product performance, intended use/indications, components, materials, sterilization method, shelf life, manufacturing process, and operating principle are identical to the currently marketed predicate devices. There are only minor shape variations between the Subject and predicate device.

Name of Device	ASAHI CHIKAI Neurovascular Guide Wire (Round Curve)	ASAHI CHIKAI Neurovascular Guide Wire
510(k)	Current Application	K110584
Intended Use and Indications	ASAHI Neurovascular Guide Wire is intended to be used in the neuro vasculature to facilitate the placement and exchange of therapeutic devices such as cerebral catheters during intravascular therapy. This guide wire is intended for use only in the neuro vasculature.	
Sterilization	Provided sterile via Ethylene Oxide to SAL10 <sup>-6</sup>	
Shelf Life	3 Years	
Target Body Location	Neuro Vascular	
Outer Distal Hydrophilic coating	Yes	
Proximal Coating	PTFE (300cm only)	
Outer Coil Material	Stainless Steel Platinum-Nickel	
Core Wire Material	Stainless Steel	
Inner Coil Material	Stainless Steel	
Distal Tip Shape	Round Curve	Straight
Overall Length	200-300 cm	
Outer coil length	30cm	
Outer Coil Outer Diameter	0.36mm	
Distal Outer Coating	Hydrophilic	
Outer Coil	Radiopaque Coil	

**NON CLINICAL TESTING / PERFORMANCE DATA:**

Confirmatory non clinical laboratory testing was performed on the ASAHI CHIKAI Neurovascular Guide Wire (Round Curve) to determine substantial equivalence.

The following testing/assessments were performed:

- Tensile Strength
- Torque Strength
- Torqueability
- Tip Flexibility

The *in vitro* bench tests demonstrated that the ASAHI CHIKAI Neurovascular Guide Wire (Round Curve) met all acceptance criteria and performed similarly to the predicate devices. Performance data demonstrate that the device functions as intended, and has a safety and effectiveness profile that is similar to the predicate devices.

**BIOCOMPATIBILITY:**

The ASAHI CHIKAI Neurovascular Guide Wire (Round Curve) was compared to the predicate device. Based on the identical materials and manufacturing process used in the subject device to its predicate, the biocompatibility of the ASAHI CHIKAI Neurovascular Guide Wire (Round Curve) was verified to be the same as those of the predicate.

**CONCLUSION:**

The ASAHI CHIKAI Neurovascular Guide Wire (Round Curve) has identical intended use and the same or similar technological characteristics such as components, design, materials, sterilization method, shelf life and operating principles as the predicate devices. Performance data demonstrates that the device functions as intended.

Therefore, the ASAHI CHIKAI Neurovascular Guide Wire (Round Curve) is substantially equivalent to the predicate device.