DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 1, 2017

ASAHI INTECC CO., LTD.
% Candace Cederman
CardioMed Device Consultants, LLC
5523 Research Park Drive, Suite 205
Baltimore, Maryland 21228

Re: K171613
Trade/Device Name: ASAHI Neurovascular Guide Wire: ASAHI CHIKAI black 18 soft tip
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: MOF
Dated: May 30, 2017
Received: June 2, 2017

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,

Carlos L. Pena -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171613

Device Name

ASAHI Neurovascular Guide Wire: ASAHI CHIKAI black 18 soft tip

Indications for Use *(Describe)*

This 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

(as required by 21 CFR 807.92)

ASAHI INTECC CO.,LTD.
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Branch offices: Tokyo, Nagoya, Osaka, Hong Kong, Amsterdam, Singapore, Beijing
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ASAHI Neurovascular Guide Wire: ASAHI CHIKAI black 18 soft tip

510(k) K171613

DATE PREPARED:	June 22, 2017
APPLICANT	ASAHI INTECC CO., LTD. 1703 Wakita-cho, Moriyama-ku Nagoya, Aichi 463-0024, Japan
CONTACT	Yoshinori Terai, President and CEO ASAHI Intecc USA, Inc. 2500 Red Hill Avenue, Suite 210 Santa Ana, CA 92705 Tel: (949) 756-8252, FAX: (949) 756-8165 e-mail: ASAHI.ra-fda@ASAHI-intecc.com
TRADE NAME:	ASAHI Neurovascular Guide Wire: ASAHI CHIKAI black 18 soft tip
DEVICE CLASSIFICATION:	Class 2 per 21 CFR §870.1330
CLASSIFICATION NAME:	Wire, Guide, Catheter, Neurovasculature
PRODUCT CODE	MOF- Catheter Guide Wire
PREDICATE DEVICES:	ASAHI Neurovascular Guide Wire: ASAHI CHIKAI black 18 (K141751)

INDICATIONS FOR USE

This 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 black 18 soft tip neurovascular guide wire is a steerable guide wire with a maximum diameter of 0.018 inches (0.45mm) and length of 200cm. 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 assembly is soldered to the core wire. The coil assembly construction is similar to that of the 510(k) cleared ASAHI CHIKAI black 18 neurovascular guide wire (K141751).

The distal end of the guide wire has a radiopaque tip to achieve visibility. A hydrophilic coating is applied to the distal portion of the guidewire. Like the predicates, the ASAHI CHIKAI black 18 soft tip is packaged with accessories: a torque device, shaping device, and inserter.

This change introduces a soft tip version of the round curve tip configuration.

COMPARISON WITH PREDICATE DEVICES:

Comparisons of the ASAHI CHIKAI black 18 soft tip 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 dimensional variations in the core wire taper and inner coil between the Subject and predicate device.

Name of Device	ASAHI Neurovascular Guide Wire (ASAHI CHIKAI black 18 soft tip)	ASAHI Neurovascular Guide Wire (ASAHI CHIKAI black 18)
510(k)	Current Application	K141751
Intended Use and Indications	This 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^{-6}	
Shelf Life	3 Years	
Target Body Location	Neuro Vascular	
Outer Coil Material	Stainless Steel Platinum-Nickel	
Core Wire Material	Stainless Steel	
Inner Coil Material	Stainless Steel	
Distal Tip Shape	Round Curve	
Overall length	200 cm	
Outer coil length	34cm	
Outer Coil Outer Diameter	0.45mm	
Distal Outer Coating	Hydrophilic	
Distal Outer Coil	Radiopaque Coil	

NON CLINICAL TESTING / PERFORMANCE DATA:

The substantial equivalence of the ASAHI CHIKAI black line extension was evaluated in performance testing that followed the recommendations in the FDA guidance document: Coronary and Cerebrovascular Guidewire Guidance. Only those tests impacted by the device modifications were repeated. The table below provides a summary of the performance test methods, results and conclusions. Acceptance criteria for each of the tests were determined by prior comparative testing with predicate devices, ASAHI's established guide wire specifications, and clinical experience.

Test	Test Method Summary	Results/Conclusions
Tensile Strength	To determine maximum allowable tensile load between connections, guide wire is fixed in the Tensile Testing Machine and pulled until failure.	All test articles met established acceptance criteria. Acceptance criteria determined by evaluation of predicate devices and ASAHI's established tensile strength specifications.
Torque Strength	To determine torque strength, distal end is inserted & advanced through simulated model. Distal tip is held stationary while proximal end is rotated until failure.	All test articles met established acceptance criteria. Acceptance criteria determined by evaluation of predicate devices and ASAHI's established torque strength specifications.
Torqueability	To determine torque response, guidewire is inserted through catheter & into Rotational Response model. Proximal end is rotated and the torque response at distal end is measured.	All test articles met the acceptance criteria. Acceptance criteria determined by evaluation of predicate devices and ASAHI's established torqueability specifications.
Tip Flexibility	To determine flexibility of the distal end, the force to deflect the guide wire is measured by a force analyzer attached to a load cell.	All test articles met established Tip Flexibility acceptance criteria. Acceptance criteria determined by evaluation of predicate devices and ASAHI's established tip flexibility specifications.
Simulated Use Testing	To simulate clinical use, guidewire is inserted through guide catheter placed in simulated model and advanced to target area. Microcatheter is inserted over guidewire & advanced to target cerebral artery multiple times.	Test results on all test articles confirmed guide wire performance. Guidewire reached target area and microcatheter was successfully advanced over guidewire to target site. Acceptance criteria determined by evaluation of predicate devices and ASAHI's established simulated use specifications.

The in vitro performance tests demonstrated that the ASAHI CHIKAI black 18 soft tip met all acceptance criteria and performed similarly to the predicate device. Performance data demonstrate that the device functions as intended, and has a safety and effectiveness profile that is similar to the predicate device.

CONCLUSION:

The ASAHI CHIKAI black 18 soft tip has identical intended use and indications, 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 black 18 soft tip is substantially equivalent to the predicate device.