January 29, 2019

ASAHI INTECC CO., Ltd.
% Candace Cederman
Principal Consultant
CardioMed Device Consultants, LLC
1783 Forest Drive #254
Annapolis, Maryland 21401

Re: K183070
Trade/Device Name: ASAHI Neurovascular Guide Wire (ASAHI CHIKAI X 010)
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: MOF
Dated: October 31, 2018
Received: November 5, 2018

Dear 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Xiaolin Zheng -S

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183070

Device Name
ASAHI Neurovascular Guide Wire (ASAHI CHIKAI X 010)

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(c)]

ASAHI Neurovascular Guide Wire ASAHI® CHIKAI® X 010

510(k) K183070

DATE PREPARED:	06 January 2019
APPLICANT	ASAHI INTECC CO., LTD. 3-100 Akatsuki-cho Seto, Aichi 489-0071, Japan
CONTACT	Yoshi Terai President/CEO ASAHI INTECC USA, INC. 3002 Dow Avenue, Suite 212 Tustin, CA 92780 Tel: (949) 756-8252, FAX: (949) 756-8165 e-mail: ASAHI.ra-fda@ASAHI-intecc.com
TRADE NAME:	ASAHI® Neurovascular Guide Wire (ASAHI® CHIKAI® X 010)
DEVICE CLASSIFICATION:	Class 2 per 21 CFR §870.1330
CLASSIFICATION NAME:	Catheter, Guide, Wire
PRODUCT CODE	MOF- Catheter Guide Wire
PREDICATE DEVICES:	ASAHI® Neurovascular Guide Wire ASAHI® CHIKAI® 008, ASAHI® CHIKAI® black 18 (K141751)
REFERENCE DEVICES:	ASAHI SION (K100578)

INTENDED USE/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 Neurovascular Guide Wire (ASAHI® CHIKAI® X 010) consists of a core wire and a coil assembly. The coil assembly consists of a stainless steel distal safety wire and an outer coil, soldered to the core wire. The outer coil is radiopaque so as to easily confirm its position under radioscopy. In addition, coatings are applied on the surface of the ASAHI Neurovascular Guide Wire (ASAHI® CHIKAI® X 010). The coil and taper core wire of the ASAHI Neurovascular Guide Wire (ASAHI® CHIKAI® X 010) are coated with polyurethane and coated with a hydrophilic polymer upon the polyurethane coat. The distal portion of the ASAHI Neurovascular Guide Wire (ASAHI® CHIKAI® X 010) is soft in order to easily bend in accordance with the vessel curve. Accessories such as a Torque device, Shaping device and Inserter are included in the packaging of the ASAHI Neurovascular Guide Wire (ASAHI® CHIKAI® X 010).

COMPARISON WITH PREDICATE DEVICE:

Comparisons of the ASAHI Neurovascular Guide Wire (ASAHI® CHIKAI® X 010) and the predicate devices show that the technological characteristics of the subject device such as the components, design, materials, sterilization method, shelf life and operating principle are identical or similar to the currently marketed predicate and reference devices. The subject device utilizes a distal safety wire similar to the reference device, whereas the predicate devices utilize an inner coil.

The intended use and indications for use statement of the subject device and its primary predicates are identical. There are specific design features of the subject device that are similar to the primary predicate but not identical.

Name of Device	**ASAHI Neurovascular Guide Wire ASAHI® CHIKAI® X 010**	**ASAHI Neurovascular Guide Wire ASAHI® CHIKAI® 008 ASAHI® CHIKAI® black 18**
	Subject	Predicate
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.	
Target Body Location	Neuro vasculature	
Overall Lengths	200 cm	
Nominal OD	0.010in	0.008in, 0.018in
Outer Coil Material	Platinum-Nickel	Platinum-Nickel or Platinum-Nickel/Stainless Steel
Core Wire Material	Stainless Steel	
Hydrophilic coating	Yes	
Sterilization	Provided sterile via Ethylene Oxide to SAL10^{-6}	
Shelf Life	3 Years	

NON CLINICAL TESTING / PERFORMANCE DATA:

Non clinical laboratory testing was performed on the ASAHI Neurovascular Guide Wire (ASAHI® CHIKAI® X 010) to determine substantial equivalence. The following testing/assessments were performed:

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 tensile strength 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 the acceptance criteria. Acceptance criteria determined by evaluation of predicate devices and ASAHI's established torque strength specifications.
Torqueability	To determine torque response, guide wire is inserted through catheter & into Rotational Response model. Proximal end is rotated from 0^0 to 720^0. Torque response at distal end is measured at each 90^0 angle.	All test articles met the acceptance criteria. Torque response is similar or better than predicate.

Test	Test Method Summary	Results/Conclusions
Tip Flexibility	To determine flexibility of the distal end, the force to deflect the guide wire 45^0 and 90^0 at 5, 10 and 20 mm from distal tip 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.
Coating Adherence	Integrity of coated outer coil & core wire is determined before, and after, pretreatment and manipulation in excess of that expected in clinical use.	Test results confirmed that the integrity of the coating was maintained during simulated clinical use in all test articles.
Coating Integrity / Particulate Characterization	The total quantity and size of the particulates generated during the simulated use of the device is measured.	Test results are similar to the predicate.
Catheter Compatibility	Catheter compatibility is evaluated by measuring the force to withdraw the guide wire that has been inserted through the test catheter.	All test articles met the acceptance criteria. Resistance to catheter withdrawal is similar or better than predicate.
Bench Testing (Simulated)	To simulate clinical use, guide wire is inserted through guide catheter placed in simulated model and advanced to target area. Interventional catheter is inserted over guide wire & advanced to target cerebral artery multiple times.	Test results on all test articles confirmed guide wire performance. Guide wire reached target area and interventional catheter was successfully advanced over guide wire to target site.

The *in vitro* bench tests demonstrated that the ASAHI Neurovascular Guide Wire (ASAHI® CHIKAI® X 010) 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 Neurovascular Guide Wire (ASAHI® CHIKAI® X 010) was compared to the predicate devices. Based on similarities of the materials used in the subject device to its predicates / reference devices, the biocompatibility of the ASAHI Neurovascular Guide Wire (ASAHI® CHIKAI® X 010) was leveraged from the predicate and reference devices.

CONCLUSION:

The ASAHI Neurovascular Guide Wire (ASAHI® CHIKAI® X 010) 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 and reference devices. Performance data demonstrates that the device functions as intended.

Therefore, the ASAHI Neurovascular Guide Wire (ASAHI® CHIKAI® X 010) is substantially equivalent to the predicate device.