



July 26, 2019

ASAHI INTECC CO., LTD  
% Cynthia Valenzuela  
Director, Regulatory Affairs  
ASAHI INTECC USA, Inc.  
3002 Dow Avenue, Suite 212  
Tustin, California 92780

Re: K191714

Trade/Device Name: ASAHI Neurovascular Guide Wire (CHIKAI X 014 soft)  
Regulation Number: 21 CFR 870.1330  
Regulation Name: Catheter Guide Wire  
Regulatory Class: Class II  
Product Code: MOF  
Dated: June 26, 2019  
Received: June 26, 2019

Dear Cynthia Valenzuela:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); 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 <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). 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 (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Xiaolin Zheng, Ph.D.  
Assistant Director  
DHT5A: Division of Neurosurgical,  
Neurointerventional  
and Neurodiagnostic Devices  
OHT5: Office of Neurological  
and Physical Medicine Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K191714

Device Name

ASAHI Neurovascular Guide Wire (CHIKAI X 014 soft)

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.

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**510(K) Summary**  
[as required by 21CFR § 807.92(c)]



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**ASAHI Neurovascular Guide Wire CHIKAI X 014 soft**

<b>DATE PREPARED:</b>	27JUN2019
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<b>TRADE NAME:</b>	ASAHI Neurovascular Guide Wire (CHIKAI X 014 soft)
<b>DEVICE CLASSIFICATION:</b>	Class II, 21CFR § 870.1330
<b>CLASSIFICATION NAME:</b>	Wire, Guide, Catheter, Neurovascular
<b>PRODUCT CODE:</b>	MOF – Catheter Guide Wire
<b>PREDICATE DEVICE(S):</b>	<b>Primary Predicate:</b> ASAHI Neurovascular Guide Wire CHIKAI (K110584) <b>Reference Device:</b> ASAHI Neurovascular Guide Wire CHIKAI black(K141751)

**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.*

**Description:**

The ASAHI Neurovascular Guide Wire CHIKAI X 014 soft (hereafter “CHIKAI X 014 soft”) is a steerable guide wire with a maximum diameter of 0.014 inches (0.36mm) and available in 200cm length. The extension wire is connected to the end of the guide wire outside the body for 200cm wire. The guide wire is constructed from a stainless steel core wire with a 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 distal end of the guide wire has a radiopaque tip to achieve visibility, and is available in a straight configuration and can be made to bend easily with the vessel curve. A hydrophilic coating is applied to the distal portion of the guide wire. The coil assembly construction is similar to the 510(K) cleared ASAHI Neurovascular Guide Wire CHIKAI with K110584.

**Comparison with Predicate Device(s):**

<b>Predicate Device:</b> ASAHI Neurovascular Guide Wire CHIKAI (K110584)	<b>Reference Device:</b> ASAHI Neurovascular Guide Wire CHIKAI black (K141751)
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Comparisons of the CHIKAI X 014 soft and predicate devices show that the technological characteristics of the CHIKAI X 014 soft such as components, design, materials, sterilization method, shelf life and operating principle are identical or similar to the currently marketed predicate device. A tabular comparison of the specific technological characteristics between the predicate device and subject device is provided below.

Name of Device	ASAHI Neurovascular Guide Wire CHIKAI X 014 soft	ASAHI Neurovascular Guidewire CHIKAI
510(K)	K191714	K110584
Intended Use and Indications	The 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	Ethylene Oxide to SAL 10 <sup>-6</sup>	
Shelf Life	1 Year	3 Years
Target Body Location	Neurovascular	
Outer Coil Material	Stainless-Steel	Stainless-Steel Platinum-Nickel Alloy
Core Wire Material	Stainless-Steel	Stainless-Steel
Inner Coil Material	Platinum-Nickel Alloy	Stainless-Steel
Distal Tip Shape	Straight	Straight
Overall Length	200cm	200cm, 300cm

Distal Section Coating length	1700mm	1700mm
Outside Diameter of Wire	0.36mm	0.36mm

Non Clinical Testing / Performance Data:

The substantial equivalence of the CHIKAI X 014 soft line extension was evaluated in bench testing that followed the recommendations in the FDA guidance document; *Coronary and Cerebrovascular Guidewire Guidance*, January 1995. Only those tests impacted by the device modifications were repeated. The table below provides a summary of the bench 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 and 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 and into Rotational Response model. Proximal end is rotated from 0° to 720°. Torque response at distal end is measured at each 90° angle.	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 45° and 90° at 5, 10, and 20mm from distal tip is measure 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 and core wire is determined before, and after, pretreatment and manipulation in excess of that expected in clinical use.	Test results confirmed the integrity of the coating was maintained during simulated clinical use in all test articles.
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	To simulate clinical use, guidewire is inserted through guide catheter placed in simulated model and advanced to target area. Microcatheter is inserted over guidewire and advanced to target cerebral artery multiple times.	Test results on all test articles confirmed guidewire performance. Guidewire reached target area and interventional catheter was successfully advanced over guide wire to target site.

The in vitro bench tests demonstrated that the CHIKAI X 014 soft 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 device.

**BIOCOMPATIBILITY:**

There have been no changes in materials of the Subject device as compared to the Predicate device. For this reason, no additional biocompatibility information is required for this Special 510(K).

**CONCLUSION:**

The CHIKAI X 014 soft 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 device. Performance data demonstrates that the device functions as intended.

Therefore, the CHIKAI X 014 soft is substantially equivalent to the predicate device.