DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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January 30, 2015

Asahi Intecc Co., Ltd.
% Mr. Semih Oktay
President
CardioMed Device Consultants LLC
5523 Research Park Drive
Suite 205
Baltimore, Maryland 21228

Re: K141751
Trade/Device Name: Asahi Neurovascular Guide Wire ASAHI CHIKAI 008,
Asahi Neurovascular Guide Wire ASAHI CHIKAI Black, and
Asahi Neurovascular Guide Wire ASAHI CHIKAI Black 18
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: MOF
Dated: December 29, 2014
Received: December 31, 2014

Dear Mr. Semih Oktay,

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. Pena -S FDA

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)*
K141751

Device Name
ASAHI Neurovascular Guide Wire ASAHI CHIKAI 008
ASAHI Neurovascular Guide Wire ASAHI CHIKAI black
ASAHI Neurovascular Guide Wire ASAHI CHIKAI black 18

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

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR Part 807.92(c).

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Date Prepared: January 27, 2015

Device Information:

Proprietary Name:	ASAHI Neurovascular Guide Wire ASAHI CHIKAI 008 ASAHI Neurovascular Guide Wire ASAHI CHIKAI black ASAHI Neurovascular Guide Wire ASAHI CHIKAI black 18
Common/Usual Name:	Guide Wire
Regulation Name:	Neurovascular Catheter Guide Wire
Regulatory Class:	Class II
Product Code:	MOF

Predicate Devices:

- Micro Therapeutics Silverspeed Hydrophilic Guidewires (K993257)
- Micro Therapeutics Mirage Hydrophilic Guidewire (K002212)
- ASAHI Neurovascular Guide Wire ASAHI CHIKAI (K110584)
- ASAHI Neurovascular Guide Wire ASAHI CHIKAI 10 (K112979)
- ASAHI Prowater and Marker Wire Guide Wires (JoWire Neo's PTCA Guide Wire K022762)
- ASAHI PTCA Guide Wire Fielder (K052022)

Device Description:
The ASAHI Neurovascular Guide Wire ASAHI CHIKAI 008, ASAHI Neurovascular Guide Wire ASAHI CHIKAI black, and the ASAHI Neurovascular Guide Wire ASAHI CHIKAI black 18 (ASAHI CHIKAI series) is a line extension of the ASAHI CHIKAI (K110584) and the ASAHI CHIKAI 10 (K112979).

The ASAHI CHIKAI series of steerable guide wires are constructed from a stainless steel core wire with a coil assembly consisting of an inner and outer coil soldered to the core wire. Distal outer diameter and tip shape of the ASAHI CHIKAI series range from 0.008 inches (0.20mm) with a straight tip for the ASAHI CHIKAI 008, to 0.014 inches (0.36mm) Round Curve or Angled 90^0 tip for the ASAHI CHIKAI black, to 0.018 inches (0.45mm) with a Round Curve tip for the ASAHI CHIKAI 18. The ASAHI CHIKAI and ASAHI CHIKAI black 18 are 200cm long, and the ASAHI CHIKAI black is available in 200cm and 300cm lengths.

Indication 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.

Comparison of Technological Characteristics
The indication, design, materials, and manufacturing methods of the ASAHI CHIKAI series are the same or similar to those used for the ASAHI CHIKAI and CHIKAI 10 neurovascular guide wires and share similarities with Micro Therapeutics' neurovascular guide wires. A summary table comparing the technological characteristics of the ASAHI CHIKAI series with the predicate neurovascular devices is shown in Table 1.

Table 1 Comparison of ASAHI CHIKAI series to the predicate devices.

MFR	**ASAHI Neurovascular Guide Wire**			**ASAHI Neurovascular Guide Wire**		**Micro Therapeutics Inc. Silverspeed Hydrophilic Guidewires**	**Micro Therapeutics Inc Mirage Hydrophilic Guidewire**
Device Name	**ASAHI CHIKAI 008**	**ASAHI CHIKAI black**	**ASAHI CHIKAI black 18**	**ASAHI CHIKAI**	**ASAHI CHIKAI 10**		
510(k)	Subject 510k			K110584	K112979	K993257	K002212
Intended 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.			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.		For general intravascular use to aid in the selective placement of catheters in the peripheral, visceral, and cerebral vasculature during diagnostic and/or therapeutic procedures.	
Class	21 CFR 870.1330, Class II			Same		Same	
Device design	Stainless Steel core wire with an outer and inner coils			Same		Stainless steel core wire with an outer coil	
Outer Coating Material	Hydrophilic PTFE – proximal 300 cm length CHIKAI black only			Hydrophilic PTFE - proximal 300cm length only		Hydrophilic	
Outer Coil OD	0.20mm	0.36mm	0.45mm	0.36mm	0.26mm	0.36, 0.41, & 0.45mm	0.20mm
Overall length	200cm	200cm, 300cm	200cm	200cm 300cm	200cm 300cm	200cm	200cm
Tip shape	Straight	Round Curve, Angled 90°	Round Curve	Straight		Straight	
Sterilizing Method/ Packaging	ETO sterilized guide wire is inserted in a tube & placed in peelable pack and then in a packaging box. CHIKAI black & black 18: Angle protector & Product fixture protective components			ETO sterilized guide wire is inserted in a tube & placed in peelable pack and then in a packaging box.		Not available	Not available

The materials used in the manufacture of the ASAHI CHIKAI series tapered core wire, coils and coating materials, and the manufacturing processes are the same as those used for ASAHI's Prowater and Marker Wire PTCA Guide Wires (K022762) and ASAHI PTCA Guide Wire Fielder (K052022), which were subject to full biocompatibility testing in accordance with ISO 10993.

Non-clinical Performance Data:

The safety and effectiveness of the ASAHI CHIKAI series line extension was evaluated in bench testing that followed the recommendations in the FDA guidance document: Coronary and Cerebrovascular Guidewire Guidance. Table 2 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.

Table 2 ASAHI CHIKAI series Bench Test Summary

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, 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. Torque response is similar or better than predicate.
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.
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	Coating integrity and particulates were evaluated. The test samples were advanced through a microcatheter to the target location, retracted and the coating inspected under magnification. All particulate matter generated during insertion/retraction of the guidewire was counted & classified by their particle sizes.	This testing characterized the coating integrity and particulate generation during simulated use.
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 (Simulated) Testing	To simulate clinical use, guidewire is inserted through guide catheter placed in simulated model and advanced to target area. Interventional catheter 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 interventional catheter was successfully advanced over guidewire to target site.

All neurovascular guide wires in the ASAHI CHIKAI series met the acceptance criteria for each of the bench tests.

Conclusion

Based on the similar indication, design and materials, and the results of the bench testing, the ASAHI CHIKAI series line extension is considered substantially equivalent to the predicate devices listed above.