November 18, 2024

Enlight Medical Technologies (Shenzhen) Co., Ltd.
Kason Gui
RA Manager
5-6/F, Building A, Xinghui Technology Industrial Park
52 Huaning Road, Xinshi Community, Dalang Street, Longhua District
Shenzhen, 518109
China

Re: K240871
Trade/Device Name: Synxess Neurovascular Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: MOF
Dated: March 30, 2024
Received: October 15, 2024

Dear Kason Gui:

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 (the 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 available 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 that the Center for Devices and Radiological Health (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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the quality system (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 QS regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the medical device report (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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Xiaolin Zheng -S

For Naira Muradyan, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240871

Device Name
Synxess Neurovascular Guidewire

Indications for Use *(Describe)*
Synxess Neurovascular Guidewire 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 guidewire 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

Synxess Neurovascular Guidewire
K240871

Submission Sponsor: Enlight Medical Technologies (Shenzhen) Co., Ltd.
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Applicant Contact: Eason Zhao
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Correspondent Contact: Kason Gui
jinpeng_gui@enlight-medical.com

Date Prepared: November 14, 2024

Subject Device
Trade Name: Synxess Neurovascular Guidewire
Common Name: Catheter Guide Wire
Classification Name: Guide, Wire, Catheter, Neurovasculature
Regulation Number: 21 CFR 870.1330
Product Code: MOF
Classification: Class II

Predicate Devices:
Predicate: ASAHI CHIKAI Neurovascular Guide Wire (K110584, product code MOF)
Predicate: ASAHI CHIKAI 10 Neurovascular Guide Wire (K112979, product code MOF)

Indications for Use Statement

Synxess Neurovascular Guidewire 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 guidewire is intended for use only in the neuro vasculature.

Device Description

The Synxess Neurovascular Guidewire is available in diameters of 0.014 inch (0.35 mm)

and 0.010 inch (0.25 mm) and has 200 cm length. The device is comprised of a core wire, coils, and coatings, and is supplied with a shaping mandrel and a torque device. The guidewire distal tip is straight and shapeable. The device is provided sterile and is for single use.

Comparison of Technological Characteristics

The subject device, Synxess Neurovascular Guidewire, is substantially equivalent to the predicate devices in terms of:

- indications for use;
- materials;
- technological characteristics;
- packaging and sterilization of devices.

The differences in technological characteristics do not raise new questions of safety and effectiveness compared to the predicate devices as outlined in the comparison table below.

Item	**Predicate Device ASAHI CHIKAI**	**Predicate Device ASAHI CHIKAI 10**	**Subject Device Synxess Neurovascular Guidewire**
510(k) Number	K110584	K112979	K240871
Regulation Number	21 CFR 870.1330		Same
Regulation Class	II		Same
Product Code	MOF		Same
Indications for Use/Intended Use	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.		Synxess Neurovascular Guidewire 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 guidewire is intended for use only in the neuro vasculature.
Anatomical Site	Neuro vasculature		Same
Function	The guidewire is used to facilitate the placement and exchange of therapeutic devices.		Same
Proximal Diameter	0.014 inch	0.010 inch	GW1410: 0.014 inch GW1010: 0.010 inch

Item	Predicate Device ASAHI CHIKAI	Predicate Device ASAHI CHIKAI 10	Subject Device Synxess Neurovascular Guidewire
Distal Diameter	0.014 inch	0.010 inch	0.010 inch
Guidewire Length	200 cm, 300 cm		200 cm
Core Wire Configuration	Stainless Steel core wire		Same
Coil Length (Tip Length)	30 cm	9.5 cm	30 cm
Coil Configuration	Platinum/Nickel and Stainless Steel coils		Platinum/Tungsten and Stainless Steel coils
Tip Type and Shape	Straight, shapeable		Same
Tip Flexibility	Standard		Same
Radiopaque Coil Location	5 cm from tip	3 cm from tip	3 cm from tip
Core Wire Material	Stainless Steel		Same
Coils Material	Platinum/Nickel and Stainless Steel		Platinum/Tungsten and Stainless Steel
Coating Material	Distal: Hydrophilic Proximal: PTFE (only 300 cm guide wire)		Same
Bonding Method	Soldering		Same
Accessory	Inserter, Shaping Device, and Torque Device		Shaping Tool, Torque Device
Packaging Configuration	Guidewire is inserted in a tube, placed in peelable pack, and then in a packaging box.		Same
Sterilization Method	Ethylene Oxide		Same
Method of Supply	Sterile/Single Use		Same
Shelf Life	3 years		Same

Testing Summary

The Synxess Neurovascular Guidewire passed all performance bench testing in accordance with internal requirements, referenced guidance and international standards as shown in the table below to support substantial equivalence of the device.

Test	Standards, Guidance, Test Method	Results
Visual Inspection	FDA Guidance for Industry and Food and Drug Administration Staff: Coronary, Peripheral, and Neurovascular Guidewires - Performance Tests and Recommended Labeling, October 2019 (thereinafter, "FDA Guidewire Guidance") and ISO	Pass

	11070	
Dimensional Verification	FDA Guidewire Guidance and ISO 11070	Pass
Simulated Use	FDA Guidewire Guidance	Pass
Tensile Strength and Tip Pull	FDA Guidewire Guidance and ISO 11070	Pass
Torque Strength	FDA Guidewire Guidance	Pass
Torqueability	FDA Guidewire Guidance	Pass
Coating Integrity	FDA Guidewire Guidance	Pass
Particulate Evaluation	FDA Guidewire Guidance	Pass
Lubricity	FDA Guidewire Guidance	Pass
Corrosion Resistance	FDA Guidewire Guidance and ISO 11070	Pass
Kink Resistance	FDA Guidewire Guidance	Pass
Tip Flexibility	FDA Guidewire Guidance	Pass
Radiopacity	FDA Guidewire Guidance and ISO 11070	Pass
Fracture Test	ISO 11070	Pass
Flexing Test	ISO 11070	Pass
Shaping Mandrel Visual and Dimensional Inspection	The shaping mandrel was examined for signs of impurities or defects. The mandrel length and outer diameter were measured.	Met acceptance criteria
Shaping Mandrel Corrosion Resistance	ISO 11070	Pass
Shaping Mandrel Tensile Strength	The tensile strength between the shaping mandrel rod and handle was measured.	Met acceptance criteria
Torque Device Visual Inspection and Simulated Use	The torque device was examined for signs of impurities or defects. Simulated use evaluated the torque device compatibility and performance.	Met acceptance criteria

Biocompatibility Testing

The Synxess Neurovascular Guidewire was assessed according to the International Standard ISO 10993-1, "Biological evaluation of medical devices. Part 1. Evaluation and testing within a risk management process." The subject device is classified as an external communicating device with circulating blood contact for a limited duration (<24 hours). The following tests were performed:

Test	Standard	Results
Cytotoxicity Study Using MTT Method	ISO 10993-5	Pass
Sensitization Study Guinea Pig Maximization Test	ISO 10993-10	Pass
Intracutaneous Reactivity Test In Rabbits	ISO 10993-23	Pass
Acute Systemic Toxicity Study In Mice	ISO 10993-11	Pass

Test	Standard	Results
Pyrogen Test In Rabbits	ISO 10993-11/ USP<151>	Pass
Hemolysis Assay-Direct Contact And Extract Methods	ISO 10993-4/ ASTM F756-17	Pass
Complement Activation SC5b-9 Assay	ISO 10993-4	Pass
Thromboresistance Evaluation In Dogs	ISO 10993-4	Pass

Sterilization Validation

The Synxess Neurovascular Guidewire is sterilized using Ethylene Oxide (EO). The EO sterilization process of the device has been validated per ISO 11135:2014. The sterilant residuals have also been tested and met the acceptance criteria per ISO 10993-7:2008. The device is labeled as "non-pyrogenic".

Shelf-Life Validation

The shelf-life of the Synxess Neurovascular Guidewire is 3 years and is validated by testing of the accelerated aged devices.

Clinical Data

No clinical testing was deemed necessary to support the substantial equivalence of the subject device.

Conclusion

The Synxess Neurovascular Guidewire has the same intended use and indications for use, and similar technological characteristics compared to the predicate ASAHI CHIKAI Neurovascular Guide Wires. The differences in technological characteristics do not raise different questions of safety and effectiveness compared to the predicate, and the nonclinical testing discussed above demonstrates that the subject device performs as intended. Therefore, the subject device is substantially equivalent to the legally marketed predicate devices ASAHI CHIKAI Neurovascular Guide Wire, K110584, and ASAHI CHIKAI 10 Neurovascular Guide Wire, K112979.