September 8, 2025

TISSIUM SA
Bahija Ikched
Senior Regulatory Project Manager
74 rue du Faubourg Saint Antoine
Paris, 75012
France

Re: K251957
Trade/Device Name: Coaptium Connect with Tissium Light
Regulation Number: 21 CFR 882.5270
Regulation Name: In Situ Polymerizing Peripheral Nerve Repair Device
Regulatory Class: Class II
Product Code: SFD
Dated: June 25, 2025
Received: August 19, 2025

Dear Bahija Ikched:

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: 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 quality systems (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 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,

Adam D. Pierce -S

Digitally signed by Adam D. Pierce -S
Date: 2025.09.08 08:29:59 -04'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine Devices
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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)*
K251957

Device Name
COAPTIUM® CONNECT with TISSIUM® LIGHT

Indications for Use *(Describe)*
COAPTIUM® CONNECT with TISSIUM® LIGHT is indicated for the sutureless repair of peripheral nerve injuries not in continuity in which a gap closure ≤ 1 cm is present or can be achieved with flexion of the extremity.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY

Submitter Information:
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Contact Person:
Bahija IKCHED
Senior Regulatory Project Manager
+33 7 61 82 59 77

Date the Summary was prepared: August 29, 2025

Name of the device:

Trade Name:	COAPTIUM® Connect with TISSIUM® LIGHT
Common Name:	COAPTIUM® Connect
Classification:	*21 CFR 882.5270 In situ polymerizing peripheral nerve repair device*
Product Code:	SFD
Model numbers:	NCOCO1575: COAPTIUM® Connect 1.5mm (D) x 7.5mm (L) NCOCO2075: COAPTIUM® Connect 2.0mm (D) x 7.5mm (L) NCOCO3075: COAPTIUM® Connect 3.0mm (D) x 7.5mm (L) NCOCO4075: COAPTIUM® Connect 4.0mm (D) x 7.5mm (L) NCOCO5075: COAPTIUM® Connect 5.0mm (D) x 7.5mm (L) NCOCO6075: COAPTIUM® Connect 6.0mm (D) x 7.5mm (L) NCOCO1510: COAPTIUM® Connect 1.5mm (D) x 10mm (L) NCOCO2010: COAPTIUM® Connect 2.0mm (D) x 10mm (L) NCOCO3010: COAPTIUM® Connect 3.0mm (D) x 10mm (L) NCOCO4010: COAPTIUM® Connect 4.0mm (D) x 10mm (L) NCOCO5010: COAPTIUM® Connect 5.0mm (D) x 10mm (L) NCOCO6010: COAPTIUM® Connect 6.0mm (D) x 10mm (L) NCOCO3015: COAPTIUM® Connect 3.0mm (D) x 15mm (L) NCOCO4015: COAPTIUM® Connect 4.0mm (D) x 15mm (L) NCOCO5015: COAPTIUM® Connect 5.0mm (D) x 15mm (L) NCOCO6015: COAPTIUM® Connect 6.0mm (D) x 15mm (L)

Predicate Device: COAPTIUM® Connect with TISSIUM® LIGHT (DEN240066 granted June 17, 2025)

Device Description:
COAPTIUM® Connect is a bioabsorbable coaptation system for sutureless peripheral nerve repair of peripheral nerves not in continuity. The system includes a single-use syringe pre-filled with a photoactive COAPTIUM® polymer, which is used to secure an implantable three-dimensional coaptation chamber to the nerve segments that are distal and proximal to a peripheral nerve injury.
The system includes implantable components, the coaptation chamber and the COAPTIUM® polymer, and three sterile disposable accessories: a silicone applicator (base and cap), a syringe tip, and a TISSIUM® Light Cover.
The coaptation chamber and the COAPTIUM® polymer are designed to serve as a protective interface between the peripheral nerve and the surrounding tissues over time and create a conduit for axonal growth across a nerve gap, without the use of sutures. They are soft and flexible and degrade through hydrolysis with a bioabsorption profile that is compatible with nerve healing.
The silicone applicator and syringe tip are designed to promote consistent and precise application of the COAPTIUM® polymer onto the coaptation chamber and adjacent peripheral nerve. The TISSIUM®

Light Cover is for use with the reusable TISSIUM® LIGHT, which polymerizes the COAPTIUM® polymer on-demand.
The components of COAPTIUM® CONNECT are supplied in single use sterile double peel packages and come in a variety of sizes. The TISSIUM® Light Cover is supplied in a single peel pouch and used as a sterile cover for the reusable TISSIUM® LIGHT.
The TISSIUM® LIGHT is supplied separately and packaged in a single wall corrugated cardboard box.

Indications for Use:
COAPTIUM® Connect with TISSIUM® LIGHT is indicated for the sutureless repair of peripheral nerve injuries not in continuity in which a gap closure ≤ 1 cm is present or can be achieved with flexion of the extremity.

Substantial Equivalence:
This Special 510(k) addresses a modification to the TISSIUM® Light Cover, a component of the granted COAPTIUM® Connect with TISSIUM® LIGHT device. The intended use is identical and technological characteristics of the modified TISSIUM® Light Cover are substantially equivalent to the original version of the TISSIUM® Light Cover (DEN240066).

Summary of Technological Characteristics:
The subject device is identical to the predicate device with respect to intended use, and technological characteristics, including device type, shape (transparent, flexible sleeve), biocompatibility, performance characteristics, mode of operation and sterilization method. The subject device has some slight differences in materials and dimensions which do not raise any new or increased risks of safety and performance. The provided risk analysis and performance verification testing demonstrates the subject device is substantially equivalent to the predicate.

Testing and Test Results:
Biocompatibility testing was performed in accordance with ISO 10993-1: 2018 – Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process, and FDA guidance document, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process", issued on September 8, 2023.
Performance verification was performed, and shelf-life and sterilization validations have been performed to existing specifications.
All testing met the existing predetermined acceptance criteria

Conclusion:
Based on performance testing and the technological characteristics, the modified COAPTIUM® Connect with TISSIUM® LIGHT meets the established performance criteria and is substantially equivalent to the predicate device.