June 17, 2025

TISSIUM SA
Clara Defraye
Director, Regulatory Affairs
74 rue du Faubourg Saint Antoine
Paris 75012
France

Re: DEN240066
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: November 21, 2024
Received: November 21, 2024

Dear Clara Defraye:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the COAPTIUM CONNECT with TISSIUM LIGHT, a prescription device under 21 CFR Part 801.109 with the following 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.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the COAPTIUM CONNECT with TISSIUM LIGHT, and substantially equivalent devices of this generic type, into class II under the generic name in situ polymerizing peripheral nerve repair device.

FDA identifies this generic type of device as:

> **In situ polymerizing peripheral nerve repair device**. An in situ polymerizing peripheral nerve repair device is intended to be used in a peripheral nerve repair procedure and is composed of, in whole or in part, starting materials that polymerize when delivered to a peripheral nerve injury.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE)

determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On November 21, 2024, FDA received your De Novo requesting classification of the COAPTIUM CONNECT with TISSIUM LIGHT. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the COAPTIUM CONNECT with TISSIUM LIGHT into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the COAPTIUM CONNECT with TISSIUM LIGHT can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Risks to Health	**Mitigation Measures**
Failed repair due to device failure or user error, leading to delayed and compromised, complicated, or precluded secondary management procedure	In vivo performance testing Human factors/usability testing Non-clinical performance testing Labeling
Adverse tissue reaction	Biocompatibility evaluation Polymerization process characterization In vivo performance testing
Tissue injury	In vivo performance testing Polymerization process characterization Non-clinical performance testing Labeling
Infection	Sterilization validation Shelf life testing Labeling

In combination with the general controls of the FD&C Act, the in situ polymerizing peripheral nerve repair device is subject to the following special controls:

(1) In vivo performance testing in a clinically relevant model and defect size must demonstrate that the device performs as intended for the repair of peripheral nerve injuries and assess device preparation and deliverability, tissue reactions to the device or degradation products, device migration, and all adverse effects.

(2) A characterization of the following chemical characteristics of the polymerization process must describe how the in situ application of the precursor materials will result in a consistent final device. All physico-chemically relevant changes to parts (iii)-(vi) below are determined to significantly affect the safety or effectiveness of the device (21 CFR 807.81(a)(3)(i)) and must be described in a premarket notification:
    (i) The technical specifications of the precursor materials and polymerization initiators including the chemical formulation, chemical analysis, appearance, and physical characteristics;
    (ii) The delivery mechanism of the precursor materials to the site of application;
    (iii) The polymerization mechanism and polymer structure;
    (iv) The intermediates or side products produced;
    (v) The degradation pathway and degradants; and
    (vi) The contribution of any initiators or quenchers to the polymer, intermediates or side products, and degradants.

(3) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be evaluated:
    (i) Characterization of the polymerized final device must be performed. Physico-chemically relevant changes to the characteristics below are determined to significantly affect the safety or effectiveness of the device (21 CFR 807.81(a)(3)(i)) and must be described in a premarket notification:
        (A) The polymerization mechanism and polymer structure;
        (B) The intermediates or side products produced;
        (C) The degradation pathway and degradants; and
        (D) The contribution of any initiators or quenchers to the polymer, intermediates or side products, and degradants.
    (ii) Mechanical integrity testing, including elastic modulus, compression, swelling, and rebound testing, must be performed.
    (iii) Physico-chemical testing of the polymerized device including dimensions, chemical analysis, and reaction temperature must be performed.
    (iv) Device deliverability testing with any applicator(s), initiator(s), or delivery system(s) must be performed.

(4) Human factors/usability testing must demonstrate that the intended user(s) in the intended use environment can correctly and safely use the device following the instructions for use.

(5) The tissue-contacting components of the precursor materials, intermediate or side products, degradants, and final polymerized device must be demonstrated to be biocompatible.

(6) Performance data must demonstrate the sterility of all tissue-contacting components of the device and any delivery systems.

(7) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.

(8) Labeling must include:
    (i) Instructions on proper device preparation and implantation;
    (ii) Description of the device technical parameters and all components; and

(iii) A shelf life.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the in situ polymerizing peripheral nerve repair device they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 FD&C Act; 21 CFR 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.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Nicholas Keyes at Nicholas.Keyes@fda.hhs.gov.

Sincerely,

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For David McMullen, M.D.
Director
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health