June 17, 2025

FzioMed, Inc.
% Lisa Pritchard
VP, Regulatory, Quality, Clinical & Engineering
DuVal & Associates, P.A.
825 Nicollet Mall, Suite 1820
Minneapolis, Minnesota 55402

Re: DEN240038
Trade/Device Name: Oxiplex®
Regulation Number: 21 CFR 888.3047
Regulation Name: Absorbable gel for intraoperative use in spine surgery
Regulatory Class: Class II
Product Code: QVL
Dated: July 22, 2024
Received: July 23, 2024

Dear Lisa Pritchard:

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 Oxiplex®, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> Oxiplex® is a synthetic, absorbable gel intended as an adjunct to lumbar spinal surgery in adult patients with leg pain, back pain, and neurological symptoms undergoing discectomy to reduce leg pain and neurological symptoms.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies Oxiplex®, and substantially equivalent devices of this generic type, into Class II under the generic name absorbable gel for intraoperative use in spine surgery.

FDA identifies this generic type of device as:

> **Absorbable gel for intraoperative use in spine surgery**. This device is an absorbable gel implant for intraoperative use in spinal procedures that is applied to nerve roots after hemostasis has been achieved and prior to closure. The device is intended as an adjunct to the surgical procedure to reduce pain and neurological symptoms.

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 July 23, 2024, FDA received your De Novo requesting classification of Oxiplex®. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify Oxiplex® 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, Oxiplex® 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**
Adverse tissue reaction	Biocompatibility evaluation Pyrogenicity testing Animal performance testing
Infection	Sterilization validation Shelf life testing and packaging validation Labeling
Tissue injury resulting from: • User error/improper device use • Device swelling • Byproduct formation from device breakdown	Clinical performance data Animal performance testing Non-clinical performance testing Labeling
Pain	Clinical performance data Labeling
Neurological (sensory/motor) deterioration	Clinical performance data Labeling

In combination with the general controls of the FD&C Act, the absorbable gel for intraoperative use in spine surgery is subject to the following special controls:

(1) Clinical performance data must demonstrate that the device performs as intended under anticipated conditions for use and include the following:
   (i) Evaluation of clinically relevant endpoints, such as reduction in pain or neurological symptoms, in comparison to a clinically justified comparator (e.g., the surgical procedure itself); and
   (ii) Evaluation of relevant adverse events, including impaired wound healing, pain, neurological deterioration, any unanticipated adverse device effects, and subsequent surgical interventions.

(2) Animal performance testing must evaluate the safety of the device when used as intended under anticipated conditions of use. Animal testing must include histology to assess healing and tissue response at relevant timepoints over the course of healing, as well as an evaluation of device breakdown/absorption.

(3) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions for use and include the following:
   (i) Characterization of the device materials;
   (ii) Characterization of gel properties, including flow properties and homogeneity;
   (iii) Evaluation of gel swelling behavior and analysis of the impact of device swelling; and
   (iv) Evaluation of byproducts from incomplete gel formation and/or device breakdown and an analysis of any adverse effects.

(4) The patient-contacting components of the device must be demonstrated to be biocompatible.

(5) Performance data must support the sterility and pyrogenicity of the device components intended to be sterile.

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

(7) Labeling must include the following:
   (i) A shelf life;
   (ii) Identification of material composition;
   (iii) A detailed summary of the clinical testing pertinent to use of the device, including population studied, clinical outcomes and observed adverse events;
   (iv) Information regarding any limitations of the clinical data; and
   (v) Instructions for use, including specific instructions regarding surgical site observation for achieving hemostasis prior to device use, surgical site preparation, and device placement.

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 absorbable gel for intraoperative use in spine surgery 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 Thomas McNamara at Thomas.McNamara@fda.hhs.gov.

Sincerely,

Raquel A. Peat -S

RDML Raquel Peat, Ph.D., M.P.H., USPHS
Director
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health