May 1, 2026

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

Re: K253326
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: September 30, 2025
Received: September 30, 2025

Dear Lisa Pritchard:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, M.S.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253326

Please provide the device trade name(s).

Oxiplex

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

510(k) Owner: Fziomed, Inc.
231 Bonetti Drive
San Luis Obispo, CA 93401
Contact: Paul Mraz
Phone: 805.549.7222
Date prepared: April 30, 2026

Device Name: Trade Name: Oxiplex®
Common Name: Absorbable gel for spine surgery
Classification Name: Absorbable gel for intraoperative use in spine surgery
Regulation: 21 CFR §888.3047
Regulatory Classification: 2
Product Code: QVL

Predicate Devices: **Primary:** Oxiplex® (DEN240038)

Device Description:
Oxiplex® is a synthetic, absorbable, clear, flowable, viscoelastic gel that is comprised of sodium carboxymethylcellulose (CMC) and polyethylene oxide (PEO). In spinal surgery, Oxiplex gel is applied to the surface of adjacent tissues and nerve roots at the surgical site just prior to closure to reduce pain and improve patient outcomes. Oxiplex is for single use only and is provided sterile in a pre-filled syringe together with a sterile, flexible applicator for introduction of the gel during surgery. No mixing or other preparation is required. Oxiplex is non-pyrogenic and contains no human, animal, or bacterial components. No color additives are used in the device.

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.

Substantial Equivalence Comparison with the Predicate Devices
Indications for Use are identical to the primary predicate device.

The subject device (Oxiplex 1.5 mL configuration) and the selected predicate device (Oxiplex 3 mL configuration) both have the same intended use for use as an adjunctive absorbable gel for reducing leg pain and neurological symptoms. The subject device (Oxiplex 1.5 mL configuration) also has the same Indications for Use, type of use, environment of use, anatomic location, implanted material, mechanism of action, mechanism of application, max volume, syringe barrel material, syringe plunger material, applicator material, tip cap material, and sterile packaging as the predicate device. Where there is a difference between the subject device (Oxiplex 1.5 mL configuration) and the predicate device, that difference does not raise different questions of safety or effectiveness. The difference between the subject device (Oxiplex 1.5 mL configuration) and the predicate device includes individual volume only. This difference has been determined to not raise different questions of safety or effectiveness in comparison to the predicate device. The verification and validation data demonstrate that Oxiplex functions as intended. Therefore, the criteria for a substantial equivalence determination have been met.

Supporting Data
This change did not alter the material formulation or processing of Oxiplex gel. As a result, no additional bench, animal, or biocompatibility testing was required to support this change. Clinical data from DEN240038 supported clearance including additional analyses supportive of the 1.5 mL configuration. This included comparing a subset of the study subjects that received 1.5 mL or less of the Oxiplex gel to the full study cohort that received an average of 2.1 mL of the device (range 0.9 mL – 3.0 mL).

Conclusion
This traditional 510(k) describes a minor change to the volume for Oxiplex gel, offering an additional 1.5 mL configuration in addition to the original 3 mL configuration. This change did not impact the intended use, directions for use, mechanism of action, materials, type and duration of tissue contact, physical form, formulation, processing, component interactions, or storage conditions of the implantable Oxiplex gel. The available data demonstrates that the device function is as safe, as effective, and performs as well as the predicate device. The data provided supports substantial equivalence of Oxiplex 1.5 mL configuration to the predicate device.