



April 18, 2024

ZygoFix, Ltd.
% Justin Eggleton
Vice President
MCRA, LLC
803 7th Street NW
Washington, District of Columbia 20001

Re: K240085
Trade/Device Name: zLOCK Lumbar Facet Fixation System
Regulatory Class: Unclassified
Product Code: MRW
Dated: March 21, 2024
Received: March 22, 2024

Dear Justin Eggleton:

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.

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,

Colin
O'Neill -S 

Colin O'Neill, M.B.E.

Assistant Director

DHT6B: Division of Spinal Devices

OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K240085

Device Name

zLOCK Lumbar Facet Fixation System

Indications for Use (Describe)

The zLOCK Lumbar Facet Fixation System is an integrated construct comprised of a modular spacer and a single facet screw. The system is intended for temporary stabilization of the spine as an adjunct to fusion through bilateral immobilization of the facet joints in skeletally mature patients.

The zLOCK Lumbar Facet Fixation System is intended for use as an adjunct to a 1-level interbody lumbar fusion from L3 to L5 with autogenous and/or allogenic bone graft and must be accompanied by an FDA cleared intervertebral body fusion device implanted at the same spinal level. The zLOCK Lumbar Facet Fixation System is indicated for the treatment of patients with lumbar degenerative disc disease at a single level from L3 to L5 in skeletally mature patients who have failed conservative care.

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.

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510(k) Summary

Trade Name: zLOCK Lumbar Facet Fixation System

Manufacturer: ZygoFix, Ltd.
17 T'helet St.
Misgay Business Park
Misgay M.P.
2017400, Israel

Sponsor Contact: Ofer Levy
Chief Executive Officer

Prepared by: Justin Eggleton
MCRA, LLC
803 7th Street, NW, 3rd Floor
Washington, DC 20001
Office: 202.552.5800

Date Prepared: March 7, 2024

Classification: Unclassified

Product Codes: MRW; System, Facet Screw Spinal Device

Primary Predicate: PrimaLOK Facet Fixation System (K102438)

Additional Predicate: PMT Facet Fixation System, Lumbar (PMT FFS-LX) (K230840)

Reference Device: PMT Facet Fixation System (K220951)

Device Description:

The zLOCK Lumbar Facet Fixation System is composed of a modular spacer and facet screws as an integrated construct to achieve posterior lumbar facet fixation as an adjunct to fusion. All implants are supplied sterile for single use only. The modular spacers are available in one footprint with a variety of heights to accommodate varying anatomical conditions of the patient, contain a screw hole, and are bendable with toothed surfaces to firmly anchor into the joint space and contain bone graft. The facet screw is cannulated, self-tapping, with a preassembled polyaxial washer; it is provided in one size. The modular spacer and facet screw are manufactured from Titanium Grade 1 and Titanium 6Al 4V alloy, respectively.

The system is supplied with a set of non-sterile, reusable instruments to access the site, prepare it for implantation, and perform device implantation.

Indications For Use:

The zLOCK Lumbar Facet Fixation System is an integrated construct comprised of a modular spacer and a single facet screw. The system is intended for temporary stabilization of the spine as an adjunct to fusion through bilateral immobilization of the facet joints in skeletally mature patients.

The zLOCK Lumbar Facet Fixation System is intended for use as an adjunct to a 1-level interbody lumbar fusion from L3 to L5 with autogenous and/or allogenic bone graft and must be accompanied by an FDA cleared intervertebral body fusion device implanted at the same spinal level. The zLOCK Lumbar Facet Fixation System is indicated for the treatment of patients with lumbar degenerative disc disease at a single level from L3 to L5 in skeletally mature patients who have failed conservative care.

Predicate Device:

The zLOCK Lumbar Facet Fixation System is substantially equivalent in indications, design principles, and performance to the following legally marketed predicate devices:

Primary Predicate: PrimaLOK Facet Fixation System (K102438)

Additional Predicate: PMT Facet Fixation System, Lumbar (PMT FFS-LX) (K230840)

Reference Device: PMT Facet Fixation System (K220951)

Non-Clinical Performance Testing:

Non-clinical testing performed on the subject zLOCK Lumbar Facet Fixation System supports substantial equivalence to predicate devices. The following testing were presented:

- Screw Testing per ASTM F543:
 - Static axial pullout test
 - Torsional strength test
 - Insertion and removal tests
- Modular Spacer Testing per ASTM F2077:
 - Static and dynamic axial compression
 - Static and dynamic compression-shear
- Biomechanical study in cadaveric specimens
- Finite Element Analysis to evaluate shear forces

Clinical Data:

Clinical data from a prospective, multi-center single arm interventional study outside the United States was presented. Patients implanted with the zLOCK Lumbar Facet Fixation System Modular Spacer were evaluated using radiographic and CT evaluations, safety data, and patient reported outcomes (Oswestry Disability Index and visual analog scale for back and leg pain). For the proposed indications for use, the clinical data on the zLOCK device supports there are no increased safety or effectiveness concerns compared to predicates when used for lumbar facet fixation.

Substantial Equivalence:

The zLOCK Lumbar Facet Fixation System is substantially equivalent to legally marketed predicate devices in terms of its technological characteristics, intended use, and mechanical performance. The zLOCK Facet Screw is nearly identical to the primary predicate except for a minor difference in thread geometry. The zLOCK construct, consisting of a Modular Spacer with Facet Screw, has the same principles of operation as the predicate devices.

Conclusion:

The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject and predicate devices are packaged in similar materials and are sterilized using similar methods. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.