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

September 20, 2024

Re: K242650
Trade/Device Name: zLOCK Lumbar Facet Fixation System
Regulatory Class: Unclassified
Product Code: MRW
Dated: September 3, 2024
Received: September 4, 2024

Dear Mr. 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.

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,

Eileen Cadel -S

Digitally signed by Eileen Cadel -S
Date: 2024.09.20 12:14:52 -04'00'

for

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K242650

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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

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

Official Correspondent: Justin Eggleton
Vice President, Head of Musculoskeletal Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001
Phone: (202)-552-5804
jeggleton@mcra.com

Date Prepared: September 5, 2024

Trade Name: zLOCK Lumbar Facet Fixation System

Common Name: Facet Joint Fixation System

Classification: Unclassified

Product Code: MRW; System, Facet Screw Spinal Device

Primary Predicate Device: zLOCK Lumbar Facet Fixation System (K240085)

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.

The purpose of this 510(k) was to add a new screw size to the previously cleared ***zLOCK Lumbar Facet Fixation System*** (K240085) and to modify the length of the spacer component.

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.

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:

- Axial Pullout per ASTM F543
- Driving Torque per ASTM F543

Substantial Equivalence:
The subject ***zLOCK Lumbar Facet Fixation System*** is substantially equivalent to the previously cleared version in K240085 with respect to intended use, materials, design, and function.

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