



Oak Tree Engineering, LLC.
% Douglas W. Neary
Consultant
419 Main Street, #242
Huntington Beach, CA 92648

July 27, 2021

Re: K211932

Trade/Device Name: FIXXSURE™ Anterior Lumbar Plate and Screw System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: April 5, 2021
Received: June 22, 2021

Dear Douglas W. Neary:

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 (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 located 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.

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 and Part 809); 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 Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

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

Indications for Use

510(k) Number (if known)

K211932

Device Name

FIXXSURE™ Anterior Lumbar Plate and Screw System

Indications for Use (Describe)

The FIXXSURE™ Anterior Lumbar Plate and Screw System is indicated for use via the anterior, lateral or anterolateral surgical approach above the bifurcation of the great vessels or via the anterior surgical approach, below the bifurcation of the great vessels as an adjunct to fusion. This system is indicated in the treatment of lumbar and lumbosacral (L1-S1) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc conformed by patient history and radiographic studies), pseudoarthrosis, spondylolysis, scoliosis, spondylolisthesis, lordotic deformities of the spine, spinal stenosis, or a failed previous spine surgery.

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

The following 510(k) summary is being submitted as required by 21 CFR 807.92:

1 Manufacturer

Submitter:	Oak Tree Engineering, LLC.
	419 Main Street, #242, Huntington Beach, California 92648.
	Phone: 805-797-3003
	Website: https://www.oaktreellc.com
Contact Person:	Douglas W. Neary douglaswneary@aol.com
Date	April 5, 2021

2. Device Identification

Trade Name:	FIXXSURE™ Anterior Lumbar Plate and Screw System
Common Name:	Spinal Fixation Appliances
Product Code:	KWQ
Classification:	Class II
Classification Name:	Spinal intervertebral body fixation orthosis
Regulation No.	21 CFR 888.3060
Classification Pane	Orthopedic

3. Predicate or legally marketed devices which are substantially equivalent.

The FIXXSURE™ Anterior Lumbar Plate and Screw System has undergone a comprehensive battery of non-clinical testing, including chemical, physical. The testing supports a determination of substantial equivalence. The FIXXSURE™ Anterior Lumbar Plate and Screw System met all pre-defined acceptance criteria and, in tests where it was compared to either AccelFix Anterior Lumbar Plate and Screw System, the predicate or reference device, was found not to represent a new worst case. Overall, the results of the performance bench tests support the substantial equivalence of the Subject device.

The design feature and indications for use for the subject device ‘FIXXSURE™ Anterior Lumbar Plate and Screw System’ is substantially equivalent to the following predicate:

- 1) Primary Predicate Device: AccelFix Lumbar Plate System (K192481)

4 Materials

FIXXSURE™ Anterior Lumbar Plate and Screw System is manufactured from Ti-6Al-4V ELI titanium alloy (ASTM F136). This this is the same material used in the predicate devices.

5. Description of the Device

The FIXXSURE™ Anterior Lumbar Plate and Screw System's implants are a lumbar Plate System intended for use as an aid in spinal fixation. They are made of Titanium 6AL-4V Alloy (ASTM F136).

The FIXXSURE™ Anterior Lumbar Plate and Screw System consists of a variety of shapes and sizes of plates and screws.

The plate has been designed to include spikes for added stability and alignment during screw insertion. The plates feature a curvature for anatomic fit. The diameter of the screw is available from 5.5 to 6.0 mm and the length from 20 to 55 mm.

6. Indications for Use

The FIXXSURE™ Anterior Lumbar Plate and Screw System is indicated for use via the anterior, lateral or anterolateral surgical approach above the bifurcation of the great vessels or via the anterior surgical approach, below the bifurcation of the great vessels as an adjunct to fusion. This system is indicated in the treatment of lumbar and lumbosacral (L1-S1) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc conformed by patient history and radiographic studies), pseudoarthrosis, spondylolysis, scoliosis, spondylolisthesis, lordotic deformities of the spine, spinal stenosis, or a failed previous spine surgery.

7. Performance –Bench testing

The FIXXSURE™ Anterior Lumbar Plate and Screw System was tested according to ASTM F 1717-18.

- 1) Static Compression Bending Test - ASTM F1717-18
- 2) Static Tension Bending Test - ASTM F1717-18
- 3) Static Torsional Test - ASTM F1717-18
- 4) Dynamic Compression Bending Test - ASTM F1717-18

Static compression, Static tensile, Static torsion and Dynamic compression testing was performed as described in ASTM F 1717-18 to demonstrate the substantial equivalence of the FIXXSURE™ Anterior Lumbar Plate and Screw System to the predicate devices.

Bench testing to evaluate the mechanical properties of the FIXXSURE™ Anterior Lumbar Plate and Screw System showed similar or higher mechanical value than the predicate marketed devices.

8. Summary of Technology Characteristics

FIXXSURE™ Anterior Lumbar Plate and Screw System is substantially equivalent to the predicate systems in terms of design, materials, indications for use and sizing.

9. Substantial Equivalence:

FIXXSURE™ Anterior Lumbar Plate and Screw System was shown to be substantially equivalent to the predicate devices in indications for use, design, function, materials used and mechanical performance.

10. Conclusion

The information presented demonstrates the substantial equivalency of the FIXXSURE™ Anterior Lumbar Plate and Screw System to the predicate devices.