December 13, 2024

LOCK-IN USA CORP
℅ Justin Gracyalny
Regulatory Affairs Program Manager
Secure BioMed Evaluations
7828 Hickory Flat Hwy Suite 120
Woodstock, Georgia 30188

Re: K243281
Trade/Device Name: LOCK-IN Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: October 17, 2024
Received: October 17, 2024

Dear Justin Gracyalny:

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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243281

Device Name
LOCK-IN Spinal Fixation System

Indications for Use *(Describe)*
The LOCK-IN Spinal Fixation System is intended for posterior, non-cervical fixation in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.

The LOCK-IN Spinal Fixation System is intended to be used with autograft and/or allograft.

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.

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510(k) Summary

Date	December 3, 2024
Sponsor	LOCK-IN USA CORP 3411 Silverside Road, Tatnall Building #104 Wilmington, DE 19810
510(k) Contact	Secure BioMed Evaluations Justin Gracyalny, MSE 7828 Hickory Flat Highway Suite 120 Woodstock, GA 30188 770-837-2681 Regulatory@SecureBME.com
Trade Name	LOCK-IN Spinal Fixation System
Common Name	Thoracolumbosacral Pedicle Screw System
Code–Classification	NKB – Thoracolumbosacral Pedicle Screw System (21 CFR §888.3070)
Primary Predicate	K992333 Electro-Biology, Inc. EBI Omega 21™ System
Additional Predicates	K102331 LDR Spine USA SpineTune™ TL Spinal System K124058 Globus Medical Inc. CREO™ Stabilization System K151704 SIGNUS Medizintechnik GmbH DIPLOMAT® Spinal System K201457 Auxein Medical Private Limited Vertaux 5.5 mm Pedicle Screw System K203507 Zimmer Biomet Spine, Inc. Vitality® Spinal Fixation System
Device Description	The LOCK-IN Spinal Fixation System is a spinal pedicle fixation system consisting of polyaxial pedicle screws (expandable and non-expandable; cannulated and non-cannulated), rods (straight and curved), rod lockers, and crosslinks. All components are manufactured from Ti-6Al-4V ELI titanium alloy. All screws are available with either standard or spondylolisthesis head configurations. Fixation is provided via a posterior approach. The LOCK-IN Spinal Fixation System expandable pedicle screws increase screw pullout strength when compared to similarly sized conventional screws. These screws are recommended for cases when increased fixation strength is desired. The LOCK-IN Spinal Fixation System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion in the non-cervical spine, including the thoracic, lumbar and/or sacral spine (T1-S5). The LOCK-IN Spinal Fixation System consists of a variety of shapes and sizes of rods, screws, cross connectors that provide internal fixation and stabilization during bone graft healing and /or fusion mass development.

Indications for Use	The LOCK-IN Spinal Fixation System is intended for posterior, non-cervical fixation in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion. The LOCK-IN Spinal Fixation System is intended to be used with autograft and/or allograft.
Technological Characteristics	There are no significant technological differences between the subject and predicate device. Minor differences in component geometry and size offerings are addressed via performance testing and via comparison to the cleared technological additional predicates. The technological design features of the subject implants were compared to the predicate in intended use, indications for use, design, function and technology and it was demonstrated that they are substantially equivalent.
Performance Testing	Non-clinical testing was performed to demonstrate the LOCK-IN Spinal Fixation System is substantially equivalent to the listed predicate devices in accordance with "Guidance for Industry and FDA Staff, Guidance for Spinal System 510(k)s", issued May 3, 2004. The following tests were performed to show equivalency: • ASTM F543 Pedicle Screw Pull-Out, Driving Torque, and Torsional Testing • ASTM F1717 Static / Compressive Bending and Torsional Testing • ASTM F2193 Static and Dynamic Cantilever Bending Testing • ASTM F1798 Tulip Disassociation Testing • Expandable Screw Reversibility Characterization Testing • Expandable Screw Cadaver Pullout Comparative Performance Study The results of these studies show the subject LOCK-IN Spinal Fixation System is substantially equivalent to the predicate device.
Conclusions	Based on the indications for use, technological characteristics, performance testing, and comparison to the predicate device, the subject LOCK-IN Spinal Fixation System is substantially equivalent to the legally marketed predicate.