S H Pitkar Orthotools Pvt Ltd.
Vivek Mangalwedhekar
Head of Firm
Plot No. EL 32, J Block, MIDC Bhosari
Pune, Maharashtra 411026
India

September 9, 2024

Re: K240233
Trade/Device Name: Pitkar Spinal Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWQ
Dated: August 7, 2024
Received: August 7, 2024

Dear Vivek Mangalwedhekar:

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: 2024.09.09 09:30:21 -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)*
K240233

Device Name
Pitkar Spinal Pedicle Screw System

Indications for Use *(Describe)*
The Pitkar Spinal Pedicle Screw System is intended for non-cervical posterior and anterolateral fixation of the spine to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and/or sacral spine:
1. Degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies);
2. Spondylolisthesis;
3. Trauma (i.e., fracture or dislocation);
4. Spinal Stenosis;
5. Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis);
6. Tumor;
7. Pseudoarthrosis and/or failed previous fusion

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.

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"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

1. Submitter:	S H Pitkar Orthotools Pvt Ltd. Plot No. EL 32, J Block, MIDC Bhosari Pune, Maharashtra 411026, India
Contact Person:	Vivek Mangalwedhekar Head of Firm Telephone: +912040706464 Fax: +912046768107
Date:	04-September-2024
2. Device Name:	Pitkar Spinal Pedicle Screw System
Common or Usual Name:	Spinal Pedicle screw System
Primary Product Code & Classification Name:	**NKB-** Thoracolumbosacral pedicle screw system (21 CFR 888.3070)
Secondary Product Code & Classification Name:	**KWQ-** Spinal Devices Intervertebral Body Fixation Orthosis (21 CFR 888.3060)
Regulatory Class:	II
3. Predicate Device(s):	
• **Primary Predicate Device:**	K043578 (4CIS Spinal System and 4CIS Low Back System)
• **Additional Predicates:**	K082572(Synthes USS Polyaxial System, Synthes USS Iliosacral System), K090648 (VIPER II System), K190471 (4CIS Chiron Spinal Fixation System), K180226 (TREND II Spinal Fixation System- STEP Series), K201457 (Auxein Brand Vertaux 5.5 mm Pedicle Screw System)
• **Reference Device**	K192619 (Pitkar Locked Plating System)
4. Device Description:	The subject system (Pitkar Spinal Pedicle Screw) attaches to the spine through screw, rod, and crosslink components. Furthermore, the system is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine. All implants are manufactured from Ti-alloy per ASTM F136.

Following is a listing of implant components included in this current submission

Ti Uniloc Poly Pedicle Screw	Ti Unistar Poly Pedicle Screw
Ti Uniloc Pedicle Screw	Ti Unistar Pedicle Screw
Ti Uniloc Spinal Precut Rod	Ti Unistar Pedicle Reduction Screw
Ti Uniloc Pedicle Reduction Screw	Ti Unistar Poly Reduction Screw
Ti Trigen Domino Connector	Ti Trigen Poly Screw
Ti Uniloc D Connector	Ti Trigen Pedicle Screw
Ti Uniloc D Connector Rod	Ti Trigen Precut Rod
Ti Uniloc Poly Reduction Screw	Ti Trigen Poly Reduction Screw
Ti Elliac Connector	Ti ProMIS Poly Screw
Ti Poly Elliac Screw	Ti ProMIS Spinal Pre-Cut Rod

Ti Combi Spinal Rod	Ti ProMIS Spinal Straight Rod
Ti V Locx Pedicle Screw	ProMis Tower Screw non-fenestrated
Ti V Locx Poly Screw	

5. Indications for Use:

The Pitkar Spinal Pedicle Screw System is intended for non-cervical posterior and anterolateral fixation of the spine to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and/or sacral spine:

- Degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Trauma (i.e., fracture or dislocation)
- Spinal Stenosis,
- Deformities or curvatures (i.e., scoliosis, Kyphosis, and/or Lordosis),
- Tumor,
- Pseudoarthrosis, and failed previous fusion

6. Summary of Technological Characteristics:

The technological design features of the subject system (Pitkar Spinal Pedicle Screw System) are substantially equivalent to the primary predicate (K043578), additional predicates (K082572, K060648, K190471, K180226, and K201457), and reference device (K192619). The technological design features of the subject system implants were compared to the predicates in intended use, indications for use, design, function, and technology and it was demonstrated that they are substantially equivalent

7. Summary of Performance Data: (Nonclinical and/or Clinical)

Non-Clinical Tests:

The device performance of Pitkar Spinal Pedicle Screw System has been demonstrated against applicable standards ASTM F1717- Standard Test Methods For Spinal Implant Constructs In A Vertebrectomy Model

- Static Compression Bending Test
- Dynamic Compression Bending Test
- Static Torsion Test

8. Conclusion:

The Pitkar Spinal Pedicle Screw System is substantially equivalent to the predicate device in which the basic design features and intended uses are the same. Any differences between the proposed device and the predicate device are considered minor and do not raise different questions concerning safety or effectiveness.
The submitted mechanical testing data demonstrates that the proposed device is substantially equivalent to that of the predicate device for the desired indications.
Based on the indications for use, technological characteristics, and the summary of data submitted, Pitkar has determined that the proposed device is substantially equivalent to the currently marketed predicate device.