March 3, 2023

SLK Ortho LLC
Lawrence Kluge
COO
5883 RFD
Long Grove, Illinois 60047

Re: K221697
Trade/Device Name: Injection Pin
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: Class II
Product Code: NDN, LOD
Dated: January 25, 2023
Received: January 26, 2023

Dear Lawrence Kluge:

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); 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,

Sara S. Thompson -S

For

Laura C. Rose, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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)*
K221697

Device Name
Injection Pin

Indications for Use *(Describe)*
Indication
The Injection Pin, is indicated for fractures caused by severe osteoporosis, trauma, and tumors of the thoracic/lumbar spine from T9-L5. Injection Pin is indicated for use in combination with PMMA bone cement (Teknimed F20®) for the treatment of fractures caused by trauma, osteoporosis, or tumors in the thoracic/lumbar spine from T9-L5.

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 last revision: March 3, 2023

I. SUBMITTER

SLK ORTHO LLC
5883 RFD
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Phone: (847) 630-1818
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Small Business Decision Number: SBD228450
FDA User Fee Organization Number: 664743

Official Correspondent

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Establishment Number

Small Business Decision Number: SBD228450
FDA User Fee Organization Number: 664743

II. DEVICE

Name of Device: Injection Pin
Common/Usual Name: Injection Pin (Titanium Fenestrated Screw)
Device Classification: Class II
Regulation Number: 21 CFR 888.3027
Device Product Codes: NDN LOD

III. PREDICATE DEVICE

Hyprevention SAS
Tradename: V-STRUT© (K191709)

Reference Device:

F20® (FDA registration number: K103433), Miniars Screw (FDA registration number K143596)

The Predicate Device V-STRUT© (K191709) has not been subject to any design related recall

IV. DEVICE DESCRIPTION

The Injection Pin is a single piece of Titanium alloy (Ti 6Al 4V) that complies with ISO 5832-3 and ASTM F136. It is a fenestrated screw that is cannulated along its entire length, with lateral holes along the body that do not interfere or affect the threads. The spherical head of the screw has an internal hexagon for firm coupling with the insertion screwdriver (REF IPST0007).

The Injection Pin implant is a medical device to be placed in the thoracolumbar region through a minimally invasive procedure. This device being cannulated and fenestrated permits the use, when applicable, for the introduction of approved PMMA (Teknimed F20®). It is available in both 5 and 6mm diameters and in lengths 31-61mm in 3mm increments.
The Injection Pin is easily seen Intra-Operatively as well as post-Op with good visualization.

V. INDICATIONS FOR USE

The Injection Pin is indicated for fractures caused by severe osteoporosis, trauma, and tumors of the thoracic/lumbar spine from T9-L5. Injection Pin is indicated for use in combination with PMMA bone cement (Teknimed F20®) for the treatment of fractures caused by trauma, osteoporosis, or tumors in the thoracic/lumbar spine from T9-L5.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE

COMPARISON	INJECTION PIN	V STRUT©
CLASSIFICATION	CLASS II	CLASS II
PICTURES		
REGULATION	21 CFR 888.3027	21 CFR 888.3027
PRODUCT CODE	NDN, LOD	NDN, LOD
INDICATIONS	Indicated for use in fractures caused by severe osteoporosis, trauma, and tumors of the thoracic/lumbar spine from T9-L5. Indicated for use in combination with PMMA bone cement (Teknimed F20®).	Indicated for use in combination with PMMA bone cement (Teknimed F20®) for the treatment of fractures caused by trauma, osteoporosis, or tumors in the thoracic/lumbar spine from T9-L5.
IMPLANT MATERIAL	Titanium alloy (Ti 6Al 4V) that complies with ISO 5832-3 and ASTM F136.	PEEK-OPTIMA™ Polymer LT1 (ASTM F2026) Tantalum markers.
IMPLANT SIZES	Dia. 5.0/6.0mm in lengths 31-61mm (3mm inc)	Pedicle access diameter: 5 mm Stacked spiral diameter: 20 mm Height: up to 15 mm
SINGLE USE	Yes	Yes
STERILE	Yes	Yes
CANNULATED	Yes	Yes
Instruments	Injection Pin Screwdriver	V-Strut Instrumentation kit

VII. PERFORMANCE DATA

Biomechanical

According to EN ISO 14602:2011 (ISO 14602:2010), intended uses are summarized in the following:

- fracture treatment of T9-L5 vertebras.
- tumor treatment of T9-L5 vertebras.

The device Injection Pin is intended in association with PMMA (Teknimed F20®) bone cement.

The Injection Pin device was subjected to mechanical testing and simulations.
Injection Pin was tested at the Polytechnic University of Milan, Dept. of Structural Engineering
Bending and torsional tests was performed applying the worst-case loading scenario.

Bone cement injection testing was conducted to verify that the injection pin is compatible with, and capable of, delivering Teknimed F20® cement under worst-case conditions.

In silico simulation in Labs of Politecnico di Milano was validated to perform 4 different scenarios in comparison with predicate device V-Strut. The in-silico approach was consistent with the biomechanical behavior of a representative osteoporotic vertebra after augmentation according to different force-displacement curves, stiffness, and maximum forces. The Injection Pin device demonstrated substantially equivalent biomechanical behavior to the predicate V-strut device.

Biocompatibility

Biocompatibility testing was conducted and documented as recommended by FDA's Guidance for Industry and FDA Staff, "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process."
Injection Pin was tested to be non-cytotoxic according to ISO 10993-1 – PART 5
Injection Pin was tested to be non-pyrogenic according to ISO 10993-1
ETO and ECH residual were performed after EO sterilization process.
Comparison with "marketed device" Miniars Screws (K143596) to demonstrate the safety of manufacturing process.

Sterility

Injection Pin is provided STERILE to the end user. This device is for single use only.
Each device is sterilized by Ethylene Oxide in accordance with ISO 11135-1
Level (SAL) of 10^{-6}

Shelf-life

Injection Pin is released with a maximum shelf-life of 5 years from the date of sterilization. The validation was performed in compliance with the standard UNI EN ISO 11607-1:2009, UNI EN ISO 11607-2:2006, UNI EN 868:2009 (relevant sections), ASTM F 1980-07:2011, ASTM F 1608-00, ASTM F 1929-98, ASTM F 1886/ F 1886-M.

VIII. SUBSTANTIAL EQUIVALENCE CONCLUSION STATEMENT

INJECTION PIN Implant (Ti 6AL 4V) compared to the predicate device V-STRUT© has demonstrated safety, effectiveness and performance as intended. Thus, a conclusion of substantial equivalence to the predicate device is supported in this submission.