September 15, 2023

Kalitec Medical
℅ Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA
803 7th Street NW
Washington, District of Columbia 20001

Re: K230974
Trade/Device Name: NIDO™ Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: September 6, 2023
Received: September 6, 2023

Dear Justin 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 (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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230974

Device Name
NIDO™ Pedicle Screw System

Indications for Use *(Describe)*
The NIDO™ Pedicle Screw System is intended 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 thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), spinal tumor, pseudarthrosis and failed previous fusion.

The NIDO™ Pedicle Screw System is also intended for non-cervical pedicle screw fixation for the following indications: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion. It is also intended for the following indications: trauma (i.e. fracture or dislocation); spinal stenosis; deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor; pseudoarthrosis; and failed previous fusion.

The NIDO™ Pedicle Screw System Cannulated/Fenestrated Screws are intended to be used with saline and radiopaque dye.

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

Trade Name: NIDO™ Pedicle Screw System

Submitter:
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Prepared By:
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Date Prepared: July 31, 2023

Device Classification: 21 CFR §888.3070, Thoracolumbosacral pedicle screw system

Common Name: Pedicle screw spinal system

Class: II

Product Code: NKB

Primary Predicate Device:

Manufacturer	Device Name	510(k) Number
Kalitec Direct LLC dba Kalitec Medical	Cosmolock Pedicle Screw System	K172808/ K140678

Reference Device:

Manufacturer	Device Name	510(k) Number
Orthofix, Inc.	JANUS® Fenestrated Screws	K180179

Indications for Use:

The NIDO™ Pedicle Screw System is intended 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 thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), spinal tumor, pseudarthrosis and failed previous fusion.

The NIDO™ Pedicle Screw System is also intended for non-cervical pedicle screw fixation for the following indications: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion. It is also intended for the following indications: trauma (i.e. fracture or dislocation); spinal stenosis; deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor; pseudoarthrosis; and failed previous fusion.

The NIDO™ Pedicle Screw System Cannulated/Fenestrated Screws are intended to be used with saline and radiopaque dye.

Device Description:

The NIDO™ Pedicle Screw System is a modular head, multiple component posterior spinal fixation system which consists of subject modular pedicle screws, screw tulips, and rod connectors manufactured from Titanium alloy Ti-6Al-4V per ASTM F136.

The subject pedicle screws are available in solid and cannulated/fenestrated configurations in various sizes to match patient anatomy. The fenestrated/cannulated screws are cannulated for use over a guidewire; they are fenestrated to allow the surgeon to apply a radiopaque dye or saline solution. The fenestrated/cannulated screws are *not* intended to allow for the use of bone cement. Screw tulips are available in standard, extended tab and closed styles, with a universal locking cap to lock the construct. Rod connectors are provided in domino, lateral and tulip styles.

The subject components are intended for use with previously cleared rods and crosslinks connectors from the primary predicate Cosmolock Pedicle Screw System.

Summary of the Technological Characteristics Compared To Predicate:

The NIDO™ Pedicle Screw System is equivalent in material, design, and manufacturing process to the listed predicate devices.

Non-Clinical Test Summary:

- Static and Dynamic Compression Bending (per ASTM F1717)
- Static Torsion (per ASTM F1717)
- Static Axial Tension (Tulip Shank Disassociation) (per ASTM F1798)
- Static Axial Gripping (per ASTM F1798)

- Static Torsional Gripping (per ASTM F1798)
- Static Flexion-Extension (per ASTM F1798)
- Axial Screw Pullout (per ASTM F543)

The results of this testing indicate that the NIDO™ Pedicle Screw System is substantially equivalent to predicate devices.

Clinical Test Summary:

No clinical studies were necessary to demonstrate substantial equivalence.

Substantial Equivalence Conclusion:

The NIDO™ Pedicle Screw System is substantially equivalent to the predicate devices listed above. This conclusion is based upon the device's similarities in principles of operation, technology, materials and indications for use.