December 13, 2023

Kalitec Direct, LLC doing business as Kalitec Medical
% J.D. Webb
President
The OrthoMedix Group, Inc.
4313 W. 3800 S.
West Haven, Utah 84401

Re: K232572
Trade/Device Name: Kalitec Navigated Instrument System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: November 9, 2023
Received: November 13, 2023

Dear J.D. Webb:

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.

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,

Shumaya Ali -S

Shumaya Ali, MPH
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.

Submission Number *(if known)*

K232572

Device Name

Kalitec Navigated Instrument System

Indications for Use *(Describe)*

The Kalitec Navigated Instrument System is indicated for use during the preparation and placement of screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The Kalitec Navigated Instruments System reusable instruments are specifically designed for use with the Medtronic Navigation StealthStation System which are indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where reference to a rigid anatomical structure such as a vertebra can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks for the anatomy. Use of the Kalitec Navigated Instrument System instruments is limited to use only with Kalitec pedicle screw systems.

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) #: K232572

510(k) Summary

Prepared on: 2023-11-09

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Kalitec Direct, LLC doing business as Kalitec Medical
Applicant Address	618 E. South Street Suite 500 Orlando FL 32801 United States
Applicant Contact Telephone	407-545-2063
Applicant Contact	Mr. Winn Scott
Applicant Contact Email	Scott@kalitecmed.com
Correspondent Name	The OrthoMedix Group, Inc.,
Correspondent Address	4313 W. 3800 S. West Haven UT 84401 United States
Correspondent Contact Telephone	512-590-5810
Correspondent Contact	Mr. J.D. Webb
Correspondent Contact Email	jdwebb@orthomedix.net

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Kalitec Navigated Instrument System
Common Name	Stereotaxic instrument
Classification Name	Orthopedic Stereotaxic Instrument
Regulation Number	882.4560
Product Code	OLO

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K124004/K140454/	Medtronic Navigated CD Horizon Solera Screwdrivers and Taps	OLO
K140678/K172808	CosmoLock Pedicle Screw System	MNI

Device Description Summary

21 CFR 807.92(a)(4)

The Kalitec Navigated Instrument System is comprised of nonsterile, reusable instruments, including probes, taps, and drivers that can be operated manually. These instruments are designed to function with the Medtronic StealthStation® S8(v2.0.1-7) System, in combination with the Medtronic NavLock™ tracker and Medtronic SureTrak®II clamps and arrays to assist surgeons in precisely locating anatomical structures in open or minimally invasive procedures for preparation and placement of Kalitec polyaxial screws.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Kalitec Navigated Instrument System is indicated for use during the preparation and placement of screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The Kalitec Navigated Instruments System reusable instruments are specifically designed for use with the Medtronic Navigation StealthStation System which are indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where reference to a rigid anatomical structure such as a vertebra can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks for the anatomy.
Use of the Kalitec Navigated Instrument System instruments is limited to use only with Kalitec pedicle screw systems.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The Kalitec Navigated Instrument System has the same indications for use as the predicate Medtronic device.

Technological Comparison 21 CFR 807.92(a)(6)

Indications for Use: no difference
Materials: no difference
Software & Hardware Compatibility: no difference
Navigation Instrument Critical Length Dimension: no difference
Operating Principle: no difference
Sterility: no difference

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The Kalitec Navigated Instrument System dimensional analysis and positional accuracy (per ASTM F2554) validations were performed in side-by-side testing of the Medtronic® StealthStation® system and predicate device. The test results demonstrate that the Kalitec Navigated Instrument System performance is substantially equivalent to the predicate.

Not Applicable

Kallitec Direct, LLC considers the Kalitec Navigated Instrument System to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials, and indications for use.