May 27, 2022

Kalitec Medical, LLC
% J.D. Webb
President
The OrthoMedix Group, Inc.
4313 West 3800 South
West Haven, Utah 84401

Re: K220902
Trade/Device Name: Navagio Lumbar Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: March 23, 2022
Received: March 28, 2022

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 (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,

Brent Showalter, Ph.D.
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: 0MB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220902

Device Name
Navagio Lumbar Cage

Indications for Use *(Describe)*

The Navagio Lumbar Cage is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).

Navagio Lumbar Cage implants are to be used with autogenous bone graft and implanted via a transforaminal approach, or an open posterior or lateral approach. The Navagio Lumbar Cage implants are to be used with supplemental fixation. Patients should have at least (6) months of non-operative treatment prior to treatment with an intervertebral cage. Patients with previous non-fusion spinal surgery at involved level may be treated with the device.

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.

510(k) Summary
for the Navagio Lumbar Cage

In accordance with 21 CFR 807.92 of the Federal Code of Regulations the following 510(k) summary is submitted for the Navagio Lumbar Cage

1. GENERAL INFORMATION

Date Prepared:	March 23, 2022
Trade Name:	Navagio Lumbar Cage
Common Name:	Intervertebral body fusion device
Classification Name:	Intervertebral body fusion device - lumbar
Class:	II
Product Code:	MAX
CFR section:	21 CFR section 888.3080
Device panel:	Orthopedic
Primary Legally Marketed Predicate Device:	InTess Lumbar Cage – Kalitec Direct (K123100)
Secondary Legally Marketed Predicate Devices	Lucent Lumbar Interbody System- Spinal Elements (K152011)
Submitter:	Kalitec Direct, LLC doing business as Kalitec Medical 618 E. South Street, Suite 500 Orlando, FL 32801 407-545-2063 Tele 407-358-5441 Fax
Contact:	J.D. Webb 4313 W. 3800 S. West Haven, UT 84401 512-590-5810 Tele e-mail: jdwebb@orthomedix.net

2. DEVICE DESCRIPTION

The Navagio Lumbar Cage was developed as an implant for the stabilization of the lumbar spinal column. The Navagio implants have ridges on both their inferior and superior surfaces to prevent migration, and graft windows to receive bone graft, which helps facilitate bony integration. X-ray markers are integrated for visualization of the implants after surgery. The components are available in a variety of sizes to more closely match the patient's anatomy.

Materials:

Zeniva® ZA-500 PEEK conforming to ASTM F2026.
Unalloyed tantalum (ASTM F560)

3. SUBSTANTIAL EQUIVALENCE CLAIMED TO PREDICATE DEVICES

The Navagio Lumbar Cage is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.

4. INTENDED USE

The Navagio Lumbar Cage is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).

Navagio Lumbar Cage implants are to be used with autogenous bone graft and implanted via a transforaminal approach, or an open posterior or lateral approach. The Navagio Lumbar Cage implants are to be used with supplemental fixation. Patients should have at least (6) months of non-operative treatment prior to treatment with an intervertebral cage. Patients with previous non-fusion spinal surgery at involved level may be treated with the device.

5. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS COMPARED TO PREDICATE

Intended use
The Navagio Lumbar Cage was developed as an implant for the stabilization of the lumbar spinal column, same as the predicates.

Indications for Use
All of the devices comply with the indications for use specified in 21 CFR section 888.3080 for lumbar intervertebral body fusion device.

Material
The Navagio Lumbar Cage uses the same material as the predicate devices.

Design
The Navagio Lumbar Cage and the predicates are equivalent in terms of shape, material, and operating principles.

Sizes
The Navagio Lumbar Cage and the predicates are equivalent in their dimensions.

6. NON-CLINICAL TEST SUMMARY

The following tests were conducted:

- Static and dynamic compression per ASTM F2077
- Subsidence per ASTM F2267
- Expulsion

The results of this testing indicate that the Navagio Lumbar Cage is substantially equivalent to predicate devices.

7. CLINICAL TEST SUMMARY

No clinical studies were performed

8. CONCLUSIONS NONCLINICAL AND CLINICAL

Kalitec Medical considers the Navagio Lumbar Cage to be 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.