September 7, 2021

NovApproach Spine
℅ Meredith May
Director of Consulting
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K211769
Trade/Device Name: OneLIF™ Intervertebral Body Replacement System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD, MAX
Dated: June 7, 2021
Received: June 8, 2021

Dear Meredith May:

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,

for
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: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement on last page.

510(k) Number *(if known)*
K211769

Device Name
OneLIF™ Intervertebral Body Replacement System

Indications for Use *(Describe)*

The OneLIF™ Interbody Fusion System is an interbody fusion device system indicated for use in skeletally mature patients at one or more levels of the lumbosacral spine (L2-S1), in patients with the following indications: degenerative disc disease (DDD) defined as back pain with degeneration of the disc confirmed by patient history and radiographic studies, spinal deformity (degenerative scoliosis or kyphosis), spondylolisthesis or retrolisthesis, and failed previous fusion (pseudoarthrosis). Patients should have received 6 months of nonoperative treatment prior to treatment with the devices.

The OneLIF™ Interbody Fusion System is intended to be used with or without the screws which accompany the implants. These devices are intended for stand-alone use in patients with DDD or degenerative spondylolisthesis at one or two contiguous levels only when used with at least three screws per implant (including at least one screw in each endplate) and when ≤ 20° lordotic implants are used. When used at more than 2 contiguous levels, or for treatment of conditions other than DDD or degenerative spondylolisthesis, or with fewer than 3 accompanying screws, or when using implants greater than a 20° lordotic angle, the system must be supplemented by posterior fixation (e.g., pedicle screw system) cleared for use in the lumbar spine.

The implants can be placed via a variety of open or minimally invasive approaches. These include anterior and oblique approaches. The implant is designed for use with autograft bone and/or allogenic bone graft comprised of cancellous or corticocancellous bone graft.

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.

5. 510(K) SUMMARY

Submitter's Name:	NovApproach Spine, LLC
Submitter's Address:	13900 Tech City Circle, Suite 300 Alachua, FL 32615
Submitter's Telephone:	352-318-2584
Contact Person:	Meredith May MS, RAC Empirical Testing Corp. 719-337-7579 MMay@EmpiricalTech.com
Date Summary was Prepared:	07-Jun-2021
Trade or Proprietary Name:	OneLIF™ Intervertebral Body Replacement System
Common or Usual Name:	Intervertebral Fusion Device with Integrated Fixation, Lumbar
Classification:	Class II per 21 CFR §888.3080
Product Code:	OVD, MAX
Classification Panel:	Orthopedic

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The OneLIF™ Interbody implant system includes interbody cages that provide six holes designed to accept bone screws of various styles and sizes.

INDICATIONS FOR USE

The OneLIF™ Interbody Fusion System is an interbody fusion device system indicated for use in skeletally mature patients at one or more levels of the lumbosacral spine (L2-S1), in patients with the following indications: degenerative disc disease (DDD) defined as back pain with degeneration of the disc confirmed by patient history and radiographic studies, spinal deformity (degenerative scoliosis or kyphosis), spondylolisthesis or retrolisthesis, and failed previous fusion (pseudoarthrosis). Patients should have received 6 months of nonoperative treatment prior to treatment with the devices.

The OneLIF™ Interbody Fusion System is intended to be used with or without the screws which accompany the implants. These devices are intended for stand-alone use in patients with DDD or degenerative spondylolisthesis at one or two contiguous levels only when used with at least three screws per implant (including at least one screw in each endplate) and when ≤ 20° lordotic implants are used. When used at more than 2 contiguous levels, or for treatment of conditions other than DDD or degenerative spondylolisthesis, or with fewer than 3 accompanying screws, or when using implants greater than a 20° lordotic angle, the system must be supplemented by posterior fixation (e.g., pedicle screw system) cleared for use in the lumbar spine.

The implants can be placed via a variety of open or minimally invasive approaches. These include anterior and oblique approaches. The implant is designed for use with autograft bone and/or allogenic bone graft comprised of cancellous or corticocancellous bone graft.

TECHNOLOGICAL CHARACTERISTICS

The titanium alloy (per ASTM F1472) OneLIF™ Interbody implant system includes an interbody that provides six holes designed to accept bone screws of various styles and sizes. The titanium alloy (per ASTM F1472) Retention Plate fastens to the Interbody with a Retention Plate Screw.

The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are identical between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Structural support mechanism

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K150135	DIVERGENCE™ Anterior/Oblique Lumbar Fusion System	Medtronic Sofamor Danek USA	Primary
K170592	BASE Interfixated Titanium System	NuVasive	Additional
K180814	M3™ Stand-Alone Anterior Lumbar System	CoreLink	Additional

PERFORMANCE DATA

The OneLIF™ Intervertebral Body Replacement System has been tested in the following test modes:

- ASTM F2077 - Static Axial Compression
- ASTM F2077 - Static Compressive Shear
- ASTM F2077 - Dynamic Axial Compression
- ASTM F2077 - Dynamic Compressive Shear
- ASTM F2267 - Subsidence

The results of this non-clinical testing show that the strength of the OneLIF™ Intervertebral Body Replacement System is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the OneLIF™ Intervertebral Body Replacement System is substantially equivalent to the predicate device.