June 12, 2025

NovApproach Spine, LLC
℅ Hannah Taggart
Engineer & Regulatory Specialist
Empirical Technologies
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K251459
Trade/Device Name: OneLIF™ Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD, MAX
Dated: May 9, 2025
Received: May 12, 2025

Dear Hannah Taggart:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Brent Showalter -S

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K251459

Device Name

OneLIF™ Interbody Fusion 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.

7-3. 510(K) SUMMARY

Submitter's Name:	NovAppoach Spine, LLC
Submitter's Address:	13900 Tech City Circle, Suite 300 Alachua FL, 32615
Submitter's Telephone:	386-588-3408
Contact Person:	Hannah Taggart, MS Empirical Technologies 719- 457-1152 htaggart@empiricaltech.com
Date Summary was Prepared:	May 9, 2025
Trade or Proprietary Name:	OneLIF™ Interbody Fusion System
Device Classification Name:	Intervertebral Fusion Device with Integrated Fixation, Lumbar
Classification & Regulation #:	Class II per 21 CFR §888.3080
Product Code:	OVD, MAX
Classification Panel:	Spinal Devices (DHT6B)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The OneLIF™ Interbody Fusion System includes interbody cages and retention plates designed for anterior or oblique insertion techniques. The purpose of this submission is to add additional implant sizes to the previously cleared system.

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 predicates included in this submission were selected based on the best practices described in the FDA Draft Guidance document *Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission*. 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
- Material of Manufacture
- Structural Support Mechanism
- Implant Sizes
- Mechanical Performance

Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Predicate Type
K211769	OneLIF™ Intervertebral Body Replacement System	NovApproach Spine, LLC	Primary
K222561	Align	Acuity Surgical Devices, LLC	Additional

PERFORMANCE DATA

The OneLIF™ Interbody Fusion System has been previously tested per ASTM F2077 under K211769. This prior testing established substantial equivalence in mechanical. Dynamic testing per ASTM F2077 and engineering analysis was performed on the modified subject implant designs to confirm no new worst-cases to confirm substantial equivalence.

CONCLUSION

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