October 18, 2022

Amplify Surgical, Inc.
℅ Nathan Wright
Engineer & Regulatory Specialist
Empirical Technologies
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K222203
Trade/Device Name: DualXSLIM® T/PLIF
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: August 10, 2022
Received: August 10, 2022

Dear Nathan Wright:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222203

Device Name
DualXSLIM® T/PLIF

Indications for Use *(Describe)*

The Amplify Surgical DualXSLIM® T/PLIF is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients. The device is intended for use at either one or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended for use with supplemental fixation and autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. The devices are to be used in patients who have had at least six months of non-operative treatment. The Amplify Surgical DualXSLIM® T/PLIF is indicated for unilateral or bilateral implantation.
The DualXSLIM® T/PLIF implants are intended for single use.

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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K222203 - 510(K) SUMMARY

Submitter's Name:	Amplify Surgical, Inc.
Submitter's Address:	9272 Jeronimo Rd., Suite 107B Irvine, California 92618
Submitter's Telephone:	949-698-4854
Contact Person:	Nathan Wright MS Empirical Technologies 719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	August 10, 2022
Trade or Proprietary Name:	DualXSLIM® T/PLIF
Common or Usual Name:	Intervertebral Fusion Device with Bone Graft, Lumbar
Classification:	Class II per 21 CFR §888.3080
Product Code:	MAX
Classification Panel:	Orthopedic Devices – Spinal Devices (DHT6B)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The purpose of this 510(k) is to offer the DualXSLIM® T/PLIF as additional sizes and lordosis options to the previously cleared DualX (K181397).

The DualX implants are a family of expandable interbody fusion devices that expand sequentially in lateral and then vertical directions. The implants are designed to be used in minimally invasive spine surgery. The DualXSLIM® T/PLIF implants are offered in a variety of sizes to accommodate patient anatomical needs. All implant components are manufactured from Ti-6Al-4V ELI per ASTM F136.

INDICATIONS FOR USE

The Amplify Surgical DualXSLIM® T/PLIF is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients. The device is intended for use at either one or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended for use with supplemental fixation and autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. The devices are to be used in patients who have had at least six months of non-operative treatment. The Amplify Surgical DualXSLIM® T/PLIF is indicated for unilateral or bilateral implantation.

The DualXSLIM® T/PLIF implants are intended for single use.

TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. The subject device is the same to predicate device in the following ways:

- Indications for Use
- Structural support mechanism

- Expansion mechanism
- Material
- Manufacturing and Biocompatibility
- Sizes

Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Predicate Type
K181397	DualX™	Innovasive, Inc.	Primary
K171633	NuVasive® TLX Interbody System	NuVuasive, Inc.	Additional
K152475	FORZA® PTC Spacer System	Orthofix Inc.	Additional

PERFORMANCE DATA

The DualXSLIM® T/PLIF has been tested in the following test modes:

- Static & Dynamic Axial Compression per ASTM F2077
- Static & Dynamic Compression Shear per ASTM F2077
- Subsidence per ASTM F2267

The results of this non-clinical testing show that the strength of the DualXSLIM® T/PLIF is sufficient for its intended use and that the DualXSLIM® T/PLIF is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the DualXSLIM® T/PLIF is substantially equivalent to the predicate device.