October 15, 2019

Amplify Surgical Inc.
% Mr. Nathan Wright, MS
Engineer & Regulatory Specialist
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K192434
Trade/Device Name: DualX™ Lumbar Intervertebral Body Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: September 4, 2019
Received: September 5, 2019

Dear Mr. 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 Ronald P. Jean, PhD
Director (Acting)
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

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020

Indications for Use

K192434

Device Name
DualX™ Lumbar Intervertebral Body Fusion Device

Indications for Use *(Describe)*

The DualX™ 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 DualX™ PLIF is indicated for unilateral or bilateral implantation.

The DualX™ LLIF is indicated for intervertebral body fusion of the lumbar spine, from L2 to L5, 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 DualX™ TLIF 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.

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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510(K) SUMMARY

Submitter's Name:	Amplify Surgical Inc.
Submitter's Address:	27071 Cabot Road, Suite 118 Laguna Hills, CA 92653
Submitter's Telephone:	765-267-5439
Contact Person:	Nathan Wright, MS Empirical Testing Corp. 719-351-0248
Date Summary was Prepared:	03-Sept-2019
Trade or Proprietary Name:	DualX™ Lumbar Intervertebral Body Fusion Device
Common or Usual Name:	Intervertebral Fusion Device With Bone Graft, Lumbar
Classification:	Class II per 21 CFR §888.3080
Product Code:	MAX
Classification Panel:	Division of Orthopedic Devices

The purpose of this submission is to modify the layout of the sterilization trays of the DualX™ Lumbar Intervertebral Body Fusion Device to include non-sterile implants to be sterilized by the end user with no changes to the implants and instruments previously cleared under K181397.

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The DualX™ Lumbar Intervertebral Body Fusion Device implants are an expanding family of interbody fusion devices that expand sequentially in lateral and then vertical directions. The implants are designed to be used in minimally invasive spine surgery and, in the collapsed configuration, are between 12.3 mm wide (TLIF and PLIF) and 13.3mm wide (LLIF).

INDICATIONS FOR USE

The DualX™ 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 DualX™ PLIF is indicated for unilateral or bilateral implantation.

The DualX™ LLIF is indicated for intervertebral body fusion of the lumbar spine, from L2 to L5, 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 DualX™ TLIF 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 indications for use for the DualX™ Lumbar Intervertebral Body Fusion Device are identical to the indications previously cleared DualX™ Lumbar Intervertebral Body Fusion Device under K181397.

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Designation**
K181397	DualX™ Lumbar Intervertebral Body Fusion Device	Innovasive, Inc.	Primary

TECHNICAL CHARACTERISTICS

After entering the joint space, the implants expand laterally to maximize the contact area around the cortical rim of the vertebral bodies. The implants then expand vertically to maintain distraction of the vertebral bodies and maximize clearance for exiting nerve roots. The implants are binary, and each implant can only be locked out in the fully expanded state. Specific sizes are included in the system with various expanded heights to optimize the fit for the patient.

The DualX™ Lumbar Intervertebral Body Fusion Device is made from titanium that conforms to ASTM F136. The subject and predicate devices have identical technological characteristics; the modification proposed does 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
- Size

PERFORMANCE TESTING SUMMARY

In support of this Special 510(k) Device Modification Premarket Notification, mechanical testing was not required to demonstrate substantial equivalent mechanical strength since there are no modifications to the implants and instruments. The substantial equivalence of mechanical

strength for the DualX™ Lumbar Intervertebral Body Fusion Device was established in the clearance of K181397.

CONCLUSION

The subject modified DualX™ Lumbar Intervertebral Body Fusion Device is nearly identical to the previously cleared DualX™ Lumbar Intervertebral Body Fusion Device. The subject DualX™ Lumbar Intervertebral Body Fusion has identical intended uses, indications, technological characteristics, and principles of operation as the predicate. The modifications raise no new types of safety or effectiveness questions. The overall technology characteristics lead to the conclusion that the DualX™ Lumbar Intervertebral Body Fusion Device is substantially equivalent to the predicate.