



September 29, 2021

Amplify Surgical, Inc.
% Meredith L. May, MS, RAC
Director of Consulting
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K211740
Trade/Device Name: DualX®
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: August 30, 2021
Received: August 31, 2021

Dear Ms. 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,

Brent Showalter -S

Brent L. 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: January 31, 2017 See PRA Statement on last page.
510(k) Number (if known) K211740	
Device Name Amplify Surgical DualX®	
Indications for Use (Describe) The DualX® ALIF and OLIF are 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)	
PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.	
FOR FDA USE ONLY	

K211740 - 510(K) SUMMARY

Submitter's Name:	Amplify Surgical, Inc.
Submitter's Address:	9272 Jeronimo Rd. Suite 107B Irvine, CA 92618
Submitter's Telephone:	949.698.4854
Contact Person:	Meredith L. May MS, RAC Empirical Testing Corp. 719.337.7579
Date Summary was Prepared:	June 3, 2021
Trade or Proprietary Name:	DualX [®]
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 - Anterior Spine Device Branch

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The DualX 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. This submission is intended to add the ALIF and OLIF versions to the previously cleared system.

INDICATIONS FOR USE

The DualX[®] ALIF 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[®] OLIF 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[®] ALIF & OLIF Lumbar Intervertebral Body Fusion Device are similar to that of the following predicate devices:

Amplify Surgical DualX[®] ALIF & OLIF Lumbar Intervertebral Body Fusion Device

<i>510(k) Number</i>	<i>Trade or Proprietary or Model Name</i>	<i>Manufacturer</i>	<i>Designation</i>
K181397	DualX® PLIF	Amplify Surgical	Primary
K142498	MAGNIFY Spacer	Globus Medical	Additional
K113447	Rise-L	Globus Medical	Additional

TECHNOLOGICAL 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.

DualX® Lumbar Intervertebral Body Fusion Device is made from titanium that conforms to ASTM F136. 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

The differences between the subject device and primary predicate device relate to the size and shape, but the technology is the same. The subject device differs from the predicate devices in minor dimensional measurements.

PERFORMANCE DATA

The DualX® Lumbar Intervertebral Body Fusion Device was evaluated against the predicate system and has been tested in the following test modes:

- Expulsion

The results of this non-clinical testing show that the strength of the DualX® ALIF and OLIF Lumbar Intervertebral Body Fusion Devices are substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the DualX® Lumbar Intervertebral Body Fusion Device is substantially equivalent to the predicate device.

Amplify Surgical DualX® ALIF & OLIF Lumbar Intervertebral Body Fusion Device