Innovasive, Inc.
% Meredith L. May MS, RAC
Vice President
Empirical Consulting
4628 Northpark Drive
Colorado Springs, Colorado 80918

September 27, 2018

Re: K181397
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 27, 2018
Received: August 29, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

for Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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 below.

510(k) Number *(if known)*
K181397

Device Name
DualX™

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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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 below.

510(k) Number *(if known)*
K181397

Device Name
DualX™

Indications for Use *(Describe)*
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.

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)

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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 below.

510(k) Number *(if known)*
K181397

Device Name
DualX™

Indications for Use *(Describe)*
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)

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5. 510(K) SUMMARY

Submitter's Name:	Innovasive, Inc.
Submitter's Address:	26020 Acero, Ste 200 Mission Viejo, CA 92691
Submitter's Telephone:	949.698.4854
Contact Person:	Meredith L. May MS, RAC Empirical Consulting LLC 719.337.7579
Date Summary was Prepared:	27 August 2018
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 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 is similar to that of the following predicate devices:

510(k) Number	*Trade or Proprietary or Model Name*	*Manufacturer*	*Designation*
K123281	AccuLIF® TL-PEEK Cage	Coalign Innovations, Inc.	Primary
K152651	AccuLIF® TL and PL Cage	Coalign Innovations, Inc.	Additional
K120966	PULSE™ Lumbar Cage System	DePuy Spine	Additional
K171519	FLXfit™	Expanding Orthopedics	Additional
K161379	Elsa	Globus Medical, Inc.	Additional
K113447	Rise	Globus Medical, Inc.	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 destraction 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

PERFORMANCE DATA

The DualX Lumbar Intervertebral Body Fusion Device has been tested in the following test modes:

- Static axial compression per ASTM F2077
- Static compressive shear per ASTM F2077
- Dynamic axial compression per ASTM F2077
- Dynamic compressive shear per ASTM F2077
- Subsidence per ASTM F2267
- Expulsion

The results of this non-clinical testing show that the strength of the DualX Lumbar Intervertebral Body Fusion Device 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 DualX Lumbar Intervertebral Body Fusion Device is substantially equivalent to the predicate device.