Advanced Research Medical, LLC
% James A. Dunning
Principal
QPC Services, LLC
537 N. Spencer
Mesa, Arizona 85203

July 25, 2018

Re: K173947
Trade/Device Name: Lumbar Interbody Fusion System (OLLIF)
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: June 20, 2018
Received: June 28, 2018

Dear James A. Dunning:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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)*
K173947

Device Name
Lumbar Interbody Fusion System (OLLIF)

Indications for Use *(Describe)*
This system is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

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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Lumbar Interbody Fusion System (OLLIF)
Premarket Notification 510(k) Summary

DATE PREPARED	07/18/2018
MANUFACTURER	Advanced Research Medical, LLC 1519 Highway 13 East Burnsville, MN 55337
CONTACT PERSON	John D Siegel CEO 610-457-5324 John.siegel@amwspine.com
PANEL CODE	Orthopaedics/87
CLASSIFICATION NAME	MAX 888.3080 – Intervertebral Fusion Device with Bone Graft, Lumbar
CLASS	Class II
COMMON NAME	Intervertebral Body Fusion Device, Lumbar (MAX)
TRADE NAME	Lumbar Interbody Fusion System (OLLIF)
PRIMARY PREDICATE DEVICE	Python Interbody Fusion Device, Eminent Spine (K090064)
REFERENCE PREDICATE DEVICE	Buttress (Fang) Plate System, Eminent Spine (K090415)

DEVICE DESCRIPTION
The Lumbar Interbody Fusion System consists of instruments and Titanium Alloy (Ti-6Al-4V per ASTM F136) implants which will be offered in twenty-four (24) size configurations to accommodate individual patient anatomy. The implants are designed to facilitate a specific surgical technique, the Oblique Lateral Lumbar approach (OLLIF). The implants are single use and the system is provided non-sterile.

INDICATIONS and INTENDED USE
Intervertebral Body Fusion Device:

This system is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Documentation was provided to demonstrate that the Subject Lumbar Interbody Fusion System is substantially equivalent to the predicate devices: Python Interbody Fusion Device (K090064) and Buttress (Fang) Plate System (K090415). The Subject devices are substantially equivalent to the predicate device in intended use, indications for use, materials, technological characteristics, and labelling.

PERFORMANCE DATA

Static and dynamic axial compression following ASTM F2077-14. Subsidence was tested following ASTM F2267-04. The above listed pre-clinical testing on the Subject device indicate that the Lumbar Interbody Fusion System is substantially equivalent to the predicate devices.

CONCLUSION

The Lumbar Interbody Fusion System and its predicate(s) have the same intended use, to provide mechanical stability in the lumbar disc space to facilitate biologic fusion. The indications for use of the Subject device are identical to those of the predicate device. Minor differences between the Subject and predicate devices do not raise any new questions of safety or efficacy. Bench testing demonstrated that the differences do not adversely impact device mechanical performance. Based on the intended use, indications for use, technological characteristics, materials, and comparison to the predicate devices, the Lumbar Interbody Fusion System has been shown to be substantially equivalent to legally marketed predicate devices.