DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 13, 2017

HD LifeSciences LLC
% Mr. Kenneth C. Maxwell
Regulatory and Quality Specialist
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K170676
Trade/Device Name: HD Lumbar Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: May 25, 2017
Received: June 13, 2017

Dear Mr. Maxwell:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170676

Device Name
HD Lumbar Interbody System

Indications for Use *(Describe)*
The HD Lumbar Interbody System is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be used with autograft bone and allograft bone comprised of cancellous and/or corticocancellous bone.

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	HD LifeSciences LLC
Submitter's Address	38 Montvale Ave Ste 380 Stoneham, MA 02180
Submitter's Telephone	978.595.6625
Company Contact Person	Ian Helmar Chief Product Officer, Director of Engineering ianhelmar@hdlifesciences.com
Contact Person	Kenneth C. Maxwell II Empirical Testing Corp. 719.291.6874 KMaxwell@empiricalconsulting.com
Date Summary was Prepared	10 July 2017
Trade or Proprietary Name	HD Lumbar Interbody System
Common or Usual Name	Intervertebral Fusion Device With Bone Graft, Lumbar
Classification	Class II per 21 CFR §888.3080 Device Classification
Product Code	MAX
Classification Panel	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The HD Lumbar Interbody System consists of interbody fusion cages made from Ti-6Al-4V implant-grade titanium using additive manufacturing technology. The implants of the HD Lumbar Interbody System are offered in a variety of lengths, widths and cross sectional geometries to accommodate patient anatomy and surgical approach. The implants of the HD Lumbar Interbody System are also offered in various lordotic configurations to ensure proper stability and alignment of the spine for differing patient anatomy. The implants are provided sterile.

INDICATIONS FOR USE

The HD Lumbar Interbody System is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be used with autograft bone and allograft bone comprised of cancellous and/or corticocancellous bone.

The indications for use for the HD Lumbar Interbody System is similar to that of the predicates listed in Table 5-1.

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. Specifically the following characteristics are the same between the subject and predicates:

- Principle of Operation
- Indications for Use
- Materials of manufacture

Table 5-1: Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Predicate Type
K072791	OPAL Spacer	Synthes	Primary
K072253	ALIF Spacer	Synthes	Additional
K160547	Cascadia Interbody System	K2M	Additional

PERFORMANCE DATA

The Lumbar Interbody System has been tested in the following test modes:

- Static axial compression per ASTM F2077-14
- Static compressive shear per ASTM F2077-14
- Dynamic axial compression per ASTM F2077-14
- Dynamic compressive shear per ASTM F2077-14
- Static expulsion per ASTM Draft F-04.25.02.02
- Static subsidence per ASTM F2267-04
- Bacterial endotoxins test per ANSl/AAMI ST72:2011/(R) 2016, USP <161>, USP <85>, EP 2.6.14, and JP 4.01.

The results of this non-clinical testing show that the strength of the Lumbar Interbody System 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 Lumbar Interbody System is substantially equivalent to the predicate device.