HD LifeSciences LLC
John Sullivan
Director of Operations
12 Gill St Suite 4500
Woburn, Massachusetts 01801

April 28, 2020

Re: K200541
Trade/Device Name: Hive™ Stand-alone Anterior Lumbar Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD, MAX
Dated: March 2, 2020
Received: March 3, 2020

Dear John Sullivan:

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
Brent Showalter, Ph.D.
Assistant 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 **Indications for Use**	Form Approved: OMB No. 0910-0120 Expiration Date: 06/30/2020 See PRA Statement below.

510(k) Number *(if known)*
K200541

Device Name
Hive™ Stand-alone Anterior Lumbar Interbody System

Indications for Use *(Describe)*

The HD LifeSciences Hive™ Stand-alone Anterior 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. 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. These devices are intended to be used with the screws which accompany the implants. When used with the accompanying screws, these devices may be used as stand-alone interbody devices. If the accompanying screws are not used the device is intended for use with supplemental fixation.

Hyperlordotic implants (20° and greater lordosis) must be used with supplemental fixation (e.g. posterior fixation) that are cleared by the FDA for use in the lumbar spine.

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.

510(k) Summary

Submitter's Name	HD LifeSciences LLC
Submitter's Address	12 Gill St Suite 4500 Woburn, MA 01801
Company Contact Person	John Sullivan 603-234-4321
Contact Person	John Sullivan 603-234-4321 johnsullivan@hdlifesciences.com
Date Summary was Prepared	3/2/20
Trade or Proprietary Name	Hive™ Stand-alone Anterior Lumbar Interbody System
Common or Usual Name	Intervertebral Body Fusion Device
Classification	Class II per 21 CFR §888.3080
Product Code	OVD, MAX
Classification Panel	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Hive™ Lumbar Interbody Fusion System is FDA cleared under K170676. This submission describes an addition to the Anterior IBFD configurations in which the device in combination with the provided screws would serve as a stand-alone interbody fusion device. This submission adds the Hive™ Stand-alone Anterior Lumbar Interbody System to the previously cleared system, which consists of interbody fusion cages made from Ti-6Al-4V implant-grade titanium conforming to ASTM F3001 using additive manufacturing technology. The implants of the Hive™ Stand-alone Anterior 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 Hive™ Stand-alone Anterior Lumbar Interbody System are also offered in various lordotic configurations to ensure proper stability and alignment of the spine for differing patient anatomy. Implants incorporate features for fixating the device to the vertebral body in a modular stand-alone manner using either interfixated features within the intervertebral space or outer plate fixation on the anterior surface of the vertebral bodies. Inter-fixation and outer-fixation allow adjustable placement of fixation components utilizing screws and screw cover plates made from Ti-6Al-4V conforming to ASTM F136.

INDICATIONS FOR USE

The HD LifeSciences Hive™ Stand-alone Anterior 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. 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. These devices are intended to be used with the screws which accompany

the implants. When used with the accompanying screws, these devices may be used as stand-alone interbody devices. If the accompanying screws are not used the device is intended for use with supplemental fixation.

Hyperlordotic implants (20° and greater lordosis) must be used with supplemental fixation (e.g. posterior fixation) that are cleared by the FDA for use in the lumbar spine.

The indications for use for the Hive™ Stand-alone Anterior Lumbar Interbody System are similar to 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
K170676	HDLS Lumbar Interbody System	HD LifeSciences	Primary
K180814	M3 Stand-alone Anterior Lumbar System	CoreLink	Additional
K180502	S128 ALIF System	Renovis	Additional
K182195	Arco-SA Lumbar Cage System	Neurostructures	Additional

PERFORMANCE DATA

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

- Static axial compression per ASTM F2077-18
- Static compressive shear per ASTM F2077-18
- Dynamic axial compression per ASTM F2077-18
- Dynamic compressive shear per ASTM F2077-18
- Static expulsion per ASTM Draft F-04.25.02.02
- Static subsidence per ASTM F2267-04
- Screw Pullout ASTM F543-17
- Cytotoxicity (MEM Elution) ISO 10993-5
- Bacterial endotoxins test per ANSl/AAMI ST72:2019

The results of this testing battery show that the strength of the Hive™ Stand-alone Anterior 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 Hive™ Stand-alone Anterior Lumbar Interbody System is substantially equivalent to predicate devices.