August 2, 2021

Aurora Spine, Inc.
% Jeffrey Brittan
Vice President of Product Realization
Watershed Idea Foundry
1815 Aston Ave., Suite 106
Carlsbad, California 92008

Re: K210521
Trade/Device Name: DEXA-C Cervical Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: June 30, 2021
Received: July 2, 2021

Dear Jeffrey Brittan:

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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K210521

Device Name
DEXA-C Cervical Interbody System

Indications for Use *(Describe)*

The DEXA-C Cervical Interbody System is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one or two contiguous levels from C2-T1. DDD is defined as discogenic pain with the degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and autograft and/or allogenic bone graft composed of cancellous, cortical, and/or cortico-cancellous bone to facilitate fusion and is to be implanted via an open, anterior approach.

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.

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510(k) Summary: DEXA-C Cervical Interbody System

Company: Aurora Spine, Inc.
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(760) 424-2004

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CTO

Representative/ Consultant: Jeffrey Brittan
Watershed Idea Foundry
(714) 287-6780
jeffbrittan@watershedideas.com

Date Prepared: February 15, 2021

Device Name: DEXA-C Cervical Interbody System

Classification: Per 21 CFR as follows:
§888.3080 Intervertebral fusion device with bone graft, cervical
Product Code: ODP
Regulatory Class: II
Orthopedic (Spinal) Review Panel

Predicate Devices: Aurora Discovery Interbody Fusion System (K111484) – *Primary Predicate*

HD Lifesciences Cervical IBFD System (K180364)

Reference Devices: Nvision Biomedical Trigon Ti Stand-Alone Wedge Fixation System (K192645)

Aurora Spine Zip MIS Interspinous Fusion System (K133091)

Purpose:
The purpose of this submission is to request clearance for the DEXA-C Cervical Interbody System.

Device Description:
The DEXA-C Cervical Interbody System is a porous 3D-printed intervertebral body fusion device that incorporates low-, mid-, or high-density lattice pattern options. The profile of the device is rectangular with a hollow core for bone graft to promote bone integration and fusion between the endplates. The device is available in various footprints and heights to accommodate variability among patients and is manufactured from titanium alloy per ASTM F3001.

Indications for Use:
The DEXA-C Cervical Interbody System is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one or two contiguous levels from C2-T1. DDD is defined as discogenic pain with the degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and autograft and/or allogenic bone graft composed of cancellous, cortical, and/or cortico-cancellous bone to facilitate fusion and is to be implanted via an open, anterior approach.

Technological Characteristics:
The DEXA-C Cervical Interbody System implants are manufactured from titanium alloy per ASTM F3001, which has a successful history of use in the spinal implant industry and use of it in these devices does not introduce any previously unaccepted patient risks. Implants are offered in multiple footprints and heights with low-, mid-, or high-density lattice pattern options.

Performance Data:
Non-clinical mechanical testing was performed consisting of the following test modes:

- Static and dynamic axial compression, compression-shear, and torsion per ASTM F2077
- Subsidence per ASTM F2267
- Expulsion

The results of this non-clinical testing show that the strength of DEXA-C device is sufficient for its intended use. All data indicates substantial equivalence to the predicate system. Clinical data and conclusions were not needed for this device.

Basis of Substantial Equivalence:
The DEXA-C Cervical Interbody System has been found to be substantially equivalent to the predicate device with respect to technical characteristics, performance, and intended use. These systems offer equivalent interbody spacer implants in a range of sizes. The information provided within this premarket notification supports substantial equivalence of the subject device to the predicate device.