June 2, 2022

Spinal Kinetics LLC
Joyce Zhong
Regulatory Affairs Manager
501 Mercury Drive
Sunnyvale, California 94085

Re: K220861
Trade/Device Name: M6-C Artificial Cervical Disc Instruments AS
Regulation Number: 21 CFR 21 CFR §888.4515
Regulation Name: Orthopedic manual surgical instrumentation for use with total disc replacement devices
Regulatory Class: Class II
Product Code: QLQ
Dated: March 23, 2022
Received: March 24, 2022

Dear Joyce Zhong:

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
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220861

Device Name
M6-C Artificial Cervical Disc Instruments AS

Indications for Use *(Describe)*
The M6-C Artificial Cervical Disc Surgical Instruments are intended for the placement and positioning of the M6-C Artificial Cervical Disc.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Device Trade Name: M6-C Artificial Cervical Disc Instruments AS

Manufacturer: Spinal Kinetics LLC
501 Mercury Drive
Sunnyvale, CA 94085
USA

Contact Person: Joyce Zhong
Manager, Regulatory Affairs
Orthofix/Spinal Kinetics
501 Mercury Drive
Sunnyvale, CA 94085
Phone: (408) 636-2524
JoyceZhong@orthofix.com

Date Prepared: May 27, 2022

Registration Number: 3004987282

Product Code: QLQ

Classifications: Class II – 21 CFR §888.4515

Classification Name: Orthopedic manual surgical instrumentation for use with total disc replacement devices

Primary Predicate: K211757 Simplify Disc Inserter FP
M6-C Artificial Cervical Disc Instrument (G6 version) Approved via PMA P170036 and reclassified in Q200722

Reason for the 510(k) Submission: Design Changes to Fin cutters, Inserters and Instrument tray assembly.

Device Description:

The surgical implantation of the M6-C Artificial Cervical Disc requires specific surgical instruments including: a footprint template and a trial to determine the appropriate size and position of the implant; a fin cutter to create tracks in the superior and inferior vertebral endplates; and an implant inserter to place the disc into the desired position to aid in and ensure correct placement within the intervertebral space. Additionally, there is a tamp to independently adjust the posterior position of the M6-C endplates, a removal tool to remove the disc from the disc space, and general surgical instruments to assist in the distraction and mobilization of the disc space. The instruments are composed primarily of surgical stainless steel coated with ME-92 coating to increase corrosion resistance, with some instrument handles also featuring aluminum and Radel materials. Surgical instruments are provided non-sterile and are intended to be reusable.

The instruments provided in the kit include Footprint Templates, Trials, Inserters, Fin Cutters, a Tamp, Removal Tools, an Intervertebral Distractor, a Paddle Distractor, a Distractor Spacer, a Slide Hammer, a Retainer, Retainer Pins and Locking Nuts.

The M6-C Instrument Tray is multi-layered with various inserts to hold surgical instrumentation in place during handling and storage. The instrument tray is perforated to allow steam to penetrate which will allow sterilization of the contents to occur in a steam autoclave.

Indications for Use:

The M6-C™ Artificial Cervical Disc Surgical Instruments are intended for the placement and positioning of the M6-C™ Artificial Cervical Disc.

Performance Testing Summary:

M6-C Artificial Cervical Disc Instrument G7 version has been evaluated via the following performance testing:

- Impact testing
- Bend/Functional testing
- Transit testing
- Sterilization validation

The results demonstrated the performance of M6-C Artificial Cervical Disc Instrument G7 is substantially equivalent to the predicate devices.

Substantial Equivalence:

The subject device is substantially equivalent to the M6-C Artificial Cervical Disc Instrument G6 predicate devices with respect to indication, design, materials, function, and performance.

Conclusion:

M6-C Artificial Cervical Disc Instrument G7 has the same intended use, indications for use, technological characteristics as the predicate device M6-C Artificial Cervical Disc Instrument G6 version per Q200722 and K211757, and the results of performance testing demonstrate the subject device do not introduce any new question of safety or effectiveness. Therefore, the M6-C Artificial Cervical Disc Instrument G7 is substantially equivalent to the cited primary predicate.