June 21, 2024

Spinal Kinetics / Orthofix / SeaSpine
Tony John
Regulatory Affairs Program Manager
501 Mercury Drive
Sunnyvale, California 94085

Re: K241117
Trade/Device Name: M6-C™ Single Use, Disposable Instrumentation
Regulation Number: 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: April 22, 2024
Received: April 23, 2024

Dear Tony John:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Showalter -S

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241117

Device Name

M6-C™ Single Use, Disposable Instrumentation

Indications for Use *(Describe)*

The M6-C™ Single Use, Disposable Instrumentation 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.

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SpinalKinetics™

510(k) Summary

Device Trade Name:	M6-C™ Single Use, Disposable Instrumentation
Manufacturer:	Spinal Kinetics LLC 501 Mercury Drive Sunnyvale, CA 94085 USA
Contact Person:	Tony John Program Manager, Regulatory Affairs Orthofix/Spinal Kinetics/SeaSpine 3451 Plano Parkway Lewisville, TX 75056 Phone: (214) 937-2153 tonyjohn@orthofix.com
Date Prepared:	April 22, 2024
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:	K220861 - M6-C Artificial Cervical Disc Instruments AS

Reason for the 510(k) Submission:
To introduce a single-use version of the existing re-usable M6-C Cervical Surgical Instrumentation cleared under K220861.

Device Description:
The M6-C™ Artificial Cervical Disc is an intervertebral disc prosthesis designed to permit motion of a functional spinal unit in the cervical spine when replacing a degenerated native disc (PMA P170036). The surgical implantation of the M6-C Cervical Artificial 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 artificial disc into the desired position to aid in and ensure correct placement within the intervertebral space. Additionally, these are general surgical instruments to assist in the distraction and mobilization of the disc space. The single use instruments are composed primarily of reinforced polyacrylamide (PAA+50%GF) with some structural components made from surgical stainless steel and are intended to be reusable.

Indications for Use:
The M6-C™ Single Use, Disposable Instrumentation are intended for the placement and positioning of the M6-C™ Artificial Cervical Disc.

Performance Testing Summary:
M6-C™ Single Use, Disposable Instrumentation has been evaluated via the following performance testing:

- Impact Testing
- Bend/Functional Testing
- Sterilization and Biocompatibility Testing

The results demonstrated the performance of M6-C™ Single Use, Disposable Instrumentation is substantially equivalent to the reusable M6-C Artificial Cervical Disc Instrument predicate device.

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

Conclusion:
M6-C™ Single Use, Disposable Instrumentation has the same intended use, indications for use as the predicate M6-C Artificial Cervical Disc Instrument predicate. The minor difference in technological characteristics do not raise any new question of safety or effectiveness and the sterilization, biocompatibility, and performance testing demonstrates that the subject device is substantial equivalent to the predicate device.