August 19, 2022

Centinel Spine LLC
% Mr. Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, District of Columbia 20001

Re: K221848
Trade/Device Name: prodisc® C SK, prodisc® C Nova, and prodisc® C Vivo Instruments
Regulation Number: 21 CFR 888.4515
Regulation Name: Manual Instruments Designed For Use With Total Disc Replacement Devices
Regulatory Class: Class II
Product Code: QLQ
Dated: June 24, 2022
Received: June 24, 2022

Dear Mr. Eggleton:

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 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)*
K221848

Device Name
prodisc® C SK, prodisc® C Nova, and prodisc® C Vivo Instruments

Indications for Use *(Describe)*
The prodisc® C SK, prodisc® C Nova, and prodisc® C Vivo instruments are intended for the placement, positioning, and removal of the prodisc® C SK, prodisc® C Nova, and prodisc® C Vivo devices.

Type of Use *(Select one or both, as applicable)*

[X] 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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510(K) SUMMARY K221848

Device Trade Name: prodisc® C SK, prodisc® C Nova, and prodisc® C Vivo Instruments

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Date Prepared: August 17, 2022

Classification: 21 CFR §888.4515; Orthopedic manual surgical instrumentation for use with total disc replacement devices

Class: II

Product Codes: QLQ

Indications for Use:
The prodisc® C SK, prodisc® C Nova, and prodisc® C Vivo instruments are intended for the placement, positioning, and removal of the prodisc® C SK, prodisc® C Nova, and prodisc® C Vivo devices.

Device Description:
The prodisc® C SK, prodisc® C Nova, and prodisc® C Vivo Instruments enable the prodisc® C SK, prodisc® C Nova, and prodisc® C Vivo devicesto be implanted as a single unit into the disc space. Additional instruments are included to allow for the removal of the prodisc® C SK, prodisc® C Nova, and prodisc® C Vivo. The purpose of this Traditional 510(k) is to seek marketing clearance for the prodisc® C SK, prodisc® C Nova, and prodisc® C VivoInstruments.

Primary Predicate Device:
Substantial equivalence of these instruments is claimed to the Legacy prodisc C® instruments approved in P070001 prior to the down classification (Legacy prodisc C® instruments were classified in response to an Accessory Reclassification Request under Classification Order Q200722).

Technological Characteristics
The purpose of this Traditional 510(k) is to seek marketing clearance for the prodisc® C SK, prodisc® C Nova, and prodisc® C Vivo Instruments. The instrument sets include trials, keel cutters, introducers, and impactors.

Performance Testing
Testing included user testing (cadaver studies), European clinical use report, cleaning validation, and steam sterilization. All completed tests met the pre-determined acceptance criteria.

Substantial Equivalence:
The subject device was demonstrated to be substantially equivalent to the predicate devices with respect to indications, design, materials, function, manufacturing, and performance.

Conclusion:
Based on the information provided above, the prodisc® C SK, prodisc® C Nova, and prodisc® C Vivo Instruments are substantially equivalent to the cited primary predicate.