August 20, 2021

NuVasive, Inc.
% Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001

Re: K211757
Trade/Device Name: Simplify Disc Inserter FP
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: June 4, 2021
Received: June 7, 2021

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 -S

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)*
K211757

Device Name
Simplify Disc Inserter FP

Indications for Use *(Describe)*
The Simplify Disc Inserter FP is intended for the placement and positioning of the Simplify Cervical Artificial 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.

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510(k) SUMMARY

Device Trade Name: Simplify Disc Inserter FP

Manufacturer:
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Contact:
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Date Prepared: July 20, 2021

Classifications: 21 CFR §888.4515

Classification Name: Orthopedic Manual Surgical Instrumentation For Use With Total Disc Replacement Devices

Class: II

Product Codes: QLQ

Indications for Use:
The Simplify Disc Inserter FP is intended for the placement and positioning of the Simplify Cervical Artificial Disc.

Device Description:
The instrument set includes a number of surgical instruments designed to facilitate Simplify Cervical Artificial Disc implantation. The Simplify Disc Inserter FP enables the Simplify Disc to be held as a rigid construct in extension and to be inserted as a single unit into the disc space. The instrument set is intended to be used only with the Simplify Cervical Artificial Disc.

The purpose of the 510(k) submission is to improve usability of the Simplify Disc Inserter with an updated version referred to as Simplify Disc Inserter FP.

Primary Predicate Device:
The Simplify Disc Inserters were downclassified in response to an Accessory Classification Request under Classification Order Q200722. This 510(k) put forth a discussion to claim substantial equivalence to the Simplify Disc Inserters that were originally PMA Approved (P200022) prior to the downclassification.

Technological Characteristics:
The purpose of this Traditional 510(k) is to seek marketing clearance for modifications to the Simplify Disc Inserter to Simplify Disc Inserter FP utilized to insert the Simplify® Cervical Artificial Disc. The modifications include the following:

- Ejector subfeature addition
- Enlarged thumb nut
- Wider jaws

Performance Testing:
Testing included user testing, dimensional analysis, cleaning validation, and steam sterilization. All completed tests met the pre-determined acceptance criteria.

Conclusion:
The indications for use and intended use are consistent with FDA classification per Q200722. Comparisons of technological characteristics and results of performance testing demonstrate the modifications to the design do not introduce any new questions of safety or effectiveness. Therefore, the Simplify Disc Inserter FP is substantially equivalent to the cited primary predicate.