March 20, 2024

NuVasive, Inc.
Krunal Shah
Senior Regulatory Affairs Specialist
7475 Lusk Blvd.
San Diego, California 92121

Re: K240507
Trade/Device Name: NuVasive AttraX Scaffold
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: February 19, 2024
Received: February 21, 2024

Dear Krunal Shah:

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,

Jesse Muir -S Digitally signed by Jesse Muir -S
Date: 2024.03.20 11:01:14 -04'00'

Jesse Muir, PhD
Assistant Director
DHT6C: Division of Restorative, Repair and Trauma 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)*

K240507

Device Name

NuVasive AttraX Scaffold

Indications for Use *(Describe)*

AttraX Scaffold is an implant intended to fill bony voids or gaps of the skeletal system (i.e., posterolateral spine, intervertebral disc space and pelvis). These osseous defects may be surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. AttraX Scaffold resorbs and is replaced with bone during the healing process. When used in the posterolateral spine, AttraX Scaffold must be used in combination with either autogenous bone or autogenous bone marrow aspirate. When used in intervertebral body fusion procedures, AttraX Scaffold must be used in combination with either autogenous bone or autogenous bone marrow aspirate and with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

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

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular, 21 CFR §807.92, the following summary of information is provided:

A. Submitted by

Krunal Shah
Sr. Specialist, Regulatory Affairs
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 458-2272

Date Prepared: March 18, 2024

B. Device Name

Trade or Proprietary Name:	*NuVasive AttraX Scaffold*
Common or Usual Name:	Filler, Bone Void, Calcium Compound
Classification Name:	Resorbable calcium salt bone void filler device
Device Class:	Class II
Classification:	21 CFR § 888.3045
Product Code:	MQV

C. Predicate Devices

The subject *NuVasive AttraX Scaffold* is substantially equivalent to the following predicate devices:

Primary Predicate: *NuVasive AttraX Scaffold* (K172497)
Additional Predicate Device: *NuVasive AttraX Putty* (K203714)

D. Device Description

AttraX Scaffold is an osteoconductive and resorbable bone void filler consisting of hydroxyapatite/tricalcium phosphate ceramic granules premixed with a highly purified type I bovine collagen that provides cohesion between the granules and acts as an absorbent matrix for fluids. The bone graft mimics the composition of natural bone and is biocompatible. *AttraX Scaffold* provides an osteoconductive environment for promoting new bone formation while resorbing at a rate consistent with bone healing. *In situ*, the collagen and ceramic components are resorbed and replaced by new bone, similar to the resorption and remodeling observed with autogenous bone.

E. Indications for Use

AttraX Scaffold is an implant intended to fill bony voids or gaps of the skeletal system (i.e., posterolateral spine, intervertebral disc space and pelvis). These osseous defects may be surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. *AttraX Scaffold* resorbs and is replaced with bone during the healing process. When used in the posterolateral spine, *AttraX Scaffold* must be used in combination with either autogenous

bone or autogenous bone marrow aspirate. When used in intervertebral body fusion procedures, *AttraX Scaffold* must be used in combination with either autogenous bone or autogenous bone marrow aspirate and with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

F. Performance Data

The purpose of this submission is to expand the indications for use of the *NuVasive AttraX Scaffold* to include its use in the intervertebral disc space in conjunction with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

In support of the prior clearance of *AttraX Scaffold* (K172497), non-clinical testing data were submitted according to the guidance documents *Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device* (issued June 2003) and *Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile* (issued January 2024). The non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included chemical composition, physical properties, sterilization, bacterial endotoxin, packaging performance and shelf life, product shelf life, biocompatibility, and animal testing.

Additionally, *AttraX Scaffold* is composed entirely of electrically nonconductive, nonmetallic, and nonmagnetic materials, and does not have any constraints or conditions on the use in the MR environment, thus we are adding the MR Safe designation to the label. In accordance with ASTM F2503 and *Guidance for Industry and FDA Staff - Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment* (issued October 2023), a scientific rationale, rather than testing, is provided to support the MR Safe designation.

G. Substantial Equivalence

The subject device is identical to the primary predicate device *NuVasive AttraX Scaffold* (K172497) in intended use, design principle, performance, material composition, size options, manufacturing processes, packaging, and biocompatibility. The performance of the primary predicate device has previously been assessed through animal testing at the time of prior clearance with direct comparison to that of the additional predicate device.

The subject device is demonstrated to be substantially equivalent to additional predicate device, *NuVasive AttraX Putty* (K203714) with respect to intended use, indications, design principles, and performance. The subject device and additional predicate device incorporate calcium phosphate materials within a resorbable binder to perform their intended use, have similar methods of use (e.g., may be molded and packed into bone defects), and are provided in multiple size options. They are provided sterile by irradiation and are intended for single-patient and single-use.

The subject device, primary predicate device and additional predicate device have the same intended use, the same product classification and product code (MQV) and similar Indications for Use statements. The subject device and additional predicate device can be used in combination with morselized autogenous bone (as a bone graft extender) in the posterolateral spine. Alternatively, the subject device and primary predicate device can be used with autogenous bone marrow aspirate in the posterolateral spine. When used in intervertebral body fusion procedures, the subject device is indicated for use with either autogenous bone graft or bone marrow aspirate and with an intervertebral body fusion device cleared by FDA for use with a bone void filler;

whereas the additional predicate is indicated to be used alone in the intervertebral body fusion procedures with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

Notably, the indications for use language of the subject device pertaining to the intervertebral disc space retains the identical method of use (i.e., must be used in combination with either autogenous bone or autogenous bone marrow aspirate) as specified in the device's posterolateral spine indication and supported by the previously provided animal testing in K172497.

Any differences in the technological characteristics between the subject device, primary predicate, and additional predicate devices do not raise new issues or concerns of safety or efficacy.

H. Conclusions

The subject device, primary predicate device, and additional predicate device have the same intended use and similar indications for use, have the same design principles (e.g., calcium phosphate granules in resorbable binders), are similar in method of use (e.g., moldable/packable), and have similar technological characteristics. The subject device, primary predicate device, and additional predicate device are provided sterile by irradiation and are intended for single-patient and single-use. As has been established by the descriptions, information, and comparisons contained in this Premarket Notification submission, including the data from prior submissions referenced herein, the subject device *NuVasive AttraX Scaffold* has been demonstrated to be substantially equivalent to its predicate devices cleared by the Agency for commercial distribution in the U.S.