November 3, 2019

NuVasive, Incorporated
Jessica LeBlanc
Senior Specialist, Regulatory Affairs
7475 Lusk Boulevard
San Diego, California 92121

Re: K191974
Trade/Device Name: NuVasive® AttraX® Putty
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: October 3, 2019
Received: October 4, 2019

Dear Ms. Leblanc:

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,

Laurence D. Coyne, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191974

Device Name
NuVasive® AttraX® Putty

Indications for Use *(Describe)*

AttraX® Putty is an implant intended to fill bony voids or gaps of the skeletal system (i.e. posterolateral spine and pelvis) and may be used in combination with autogenous bone. These osseous defects may be surgically created or the result of traumatic injury to the bone and are not instrinsic to the stability of the bony structure. AttraX Putty resorbs and is replaced with bone during the healing process.

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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510(k) Summary - K191974

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:

Jessica LeBlanc
Senior Specialist, Regulatory Affairs
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 909-3302

Date Prepared: July 22, 2019

B. Device Name

Trade or Proprietary Name:	*NuVasive® AttraX® Putty*
Common or Usual Name:	Bone void filler
Classification Name:	Resorbable calcium salt bone void filler device
Device Class:	Class II
Regulation:	21 CFR 888.3045
Product Code:	MQV

C. Predicate Devices

The subject *AttraX Putty* is substantially equivalent to multiple predicate devices. *Progentix AttraX Putty* (K151584) serves as the primary predicate device, *CuriOs (AttraX Granules)* (K090641), *Actifuse Shape* (K080736), and the *OSferion* (K061499) serve as additional predicates.

D. Device Description

NuVasive AttraX Putty is a synthetic, osteoconductive and resorbable bone void filler device consisting of ceramic granules premixed with a polymeric binder that provides cohesion between the granules. Pressure applied by user manipulation allows the AttraX Putty to be molded into specific shapes, mixed with autograft, or contoured into a bone defect, as desired by the clinician. The subject device is identical to the primary predicate device *Progentix AttraX Putty* (K151584). No changes to the design, materials, or methods of manufacture have been made for this submission.

The purpose of this 510(k) is to expand the indications for use as a bone graft replacement based on animal and clinical data.

E. Indications for Use

AttraX® Putty is an implant intended to fill bony voids or gaps of the skeletal system (i.e. posterolateral spine and pelvis) and may be used in combination with autogenous bone. 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 Putty resorbs and is replaced with bone during the healing process.

F. Technological Characteristics

As was established in this submission, the subject *AttraX Putty* is substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and have the same technological characteristics as its predicate devices through comparison in areas including design, intended use, material composition, and function. This device does not contain software or electrical equipment.

G. Performance Data

Non-clinical testing data submitted, referenced, or relied upon supports the *in vivo* safety of *AttraX Putty*. The data also demonstrates substantial equivalence to the predicate device including chemical composition, physical properties, biocompatibility, and performance characteristics.

In addition, *AttraX Putty* was clinically evaluated in instrumented thoracolumbar posterolateral fusion in a patient and observer blinded, multicenter, prospective, randomized controlled trial. The objective of the study was to evaluate whether *AttraX Putty* used alone as a bone void filler is non-inferior to autologous bone graft (iliac crest + local bone) in instrumented posterolateral fusion. The Level I clinical evidence from this randomized controlled trial demonstrates the non-inferiority of AttraX Putty versus autologous bone graft in instrumented posterolateral spinal fusion.

H. Conclusions

Based on the indications for use, non-clinical and clinical data, and comparison to predicate devices, the subject *AttraX Putty* has been shown to be substantially equivalent to legally marketed predicate devices.