NuVasive, Incorporated
Martin Yahiro, M.D.
Director, Medical Affairs
7475 Lusk Boulevard
San Diego, California 92121

November 24, 2017

Re: K172497
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: November 6, 2017
Received: November 7, 2017

Dear Dr. Yahiro:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K172497

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 and pelvis). AttraX Scaffold must be used in combination with either autogenous bone or autogenous bone marrow aspirate in the posterolateral spine. 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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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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K172497

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:

Martin Yahiro, M.D.
Director, Medical Affairs
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 909-1800

Date Prepared: November 6, 2017

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* substantially equivalent to the primary predicate device, *NuVasive Formagraft™ Collagen Bone Graft Matrix* (K050789), and additional predicates *NuVasive AttraX Putty* (K151584) and *NuVasive AttraX Granules*[1] (K090641).

D. Device Description

The subject *AttraX Scaffold*, is an osteoconductive and resorbable bone void filler designed for use in the skeletal system. *AttraX Scaffold* consists of ceramic granules premixed with purified type I bovine collagen. The ceramic granules are identical to those cleared as CuriOs (K090641; herein after referred to by the commercial name as AttraX Granules) and identical to the granules within AttraX Putty (K151584). The collagen binder used in *AttraX Scaffold* is manufactured from the same source material as that of the primary predicate Formagraft Collagen Bone Graft Matrix (K050789). *AttraX Scaffold* will be provided sterile in single-use packages. Once hydrated with biological fluids or saline, *AttraX Scaffold* can be applied directly to bone defects or molded to fit the contours of complex bone defects.

[1] AttraX Granules is the commercial name for CuriOs™

E. Indications for Use

AttraX Scaffold is an implant intended to fill bony voids or gaps of the skeletal system (i.e., posterolateral spine and pelvis). AttraX Scaffold must be used in combination with either autogenous bone or autogenous bone marrow aspirate in the posterolateral spine. 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.

F. Technological Characteristics

As was established in this submission, the subject *AttraX Scaffold* 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 to 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

Characterization of *AttraX Scaffold* has been conducted in compliance with Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device (Document issued on: June 2, 2003) and the requirements of other applicable standards. Bench-top testing was preformed to evaluate the physicochemical and crystallographic characteristics of *AttraX Scaffold*. Data to support the substantial equivalence of the AttraX Scaffold to its predicates Formagraft and AttraX Putty, were provided by *in vivo* animal data in the intended use. The biocompatibility of the *AttraX Scaffold* is demonstrated by ISO 10993 testing and the long history of clinical use of the collagen/calcium phosphate materials for the same intended use. Bacterial endotoxin testing was performed using the limulus amebocyte lysate (LAL) method and showed that the device meets the endotoxin limits of established guidelines.

H. Conclusions

Based on the indications for use, technological characteristics, and performance comparison to its predicate devices, the subject *AttraX Scaffold* has been shown to be substantially equivalent to the legally marketed predicate devices Formagraft, AttraX Putty, and AttraX Granules.