



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:

Cynthia Adams
Regulatory Affairs Associate
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
(858) 909-1800

NOV 27 2013

Date Prepared: November 25, 2013

B. Device Name

Trade or Proprietary Name: *NuVasive® Archon Anterior Cervical Plate System*
Common or Usual Name: Cervical Plate and Screw System
Classification Name: Spinal Intervertebral Body Fixation Orthosis

Device Class: Class II
Classification: 21 CFR §888.3060
Product Code: KWQ

C. Predicate Devices

The subject *NuVasive Archon Anterior Cervical Plate System* is substantially equivalent to the following devices:

- K122910 – *NuVasive® Archon Anterior Cervical Plate System*
- K000536 – *Synthes Spine Anterior CSLP System*
- K021461 – *Medtronic Atlantis Anterior Cervical Plate System*
- K010003 – *Biomet EBI Vuelock Anterior Cervical Plate System*
- K053581 – *NuVasive SmartPlate Gradient Plus System*

D. Device Description

The *NuVasive Archon Anterior Cervical Plate System* is an anterior cervical plating system that consists of a variety of implant components including screws and plates, as well as associated manual general surgical instruments. The implants are available in a variety of different shapes and sizes to suit the individual pathology and anatomical conditions of the patient. The subject device components are manufactured from titanium alloy (Ti-6Al-4V ELI) conforming to ASTM F136 or ISO 5832-3, with a nickel-cobalt-chrome-molybdenum (MP35N) lock screw option conforming to ASTM F562.

E. Intended Use

The *NuVasive Archon Anterior Cervical Plate System* is intended for anterior screw fixation of the cervical spine. These implants have been designed to provide stabilization as an adjunct to cervical fusion.

Indications for the use of the implant system include degenerative disc disease defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and



radiographic studies, spondylolisthesis, trauma, spinal stenosis, deformity, tumor, pseudarthrosis or failed previous fusion. Additionally, the three-hole version of the implant system may be appropriate only for patients with large vertebral bodies, and is particularly suited for use following corpectomies for the treatment of tumors and burst fractures.

WARNING: The *NuVasive Archon Anterior Cervical Plate System* is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

F. Technological Characteristics

As was established in this submission, the subject *Archon Anterior Cervical Plate System* 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, function, and range of sizes.

G. Performance Data

Finite Element Analysis and comparative methods, as well as a retrospective clinical literature review, were used to demonstrate that the subject *Archon Anterior Cervical Plate System* is substantially equivalent to *Archon Anterior Cervical Plate System* (K122910). The addition of the *Archon Anterior Cervical Plate System* wide plate configuration does not present a new worst-case; therefore, mechanical testing submitted and cleared through the *Archon Anterior Cervical Plate System* (K122910) may be adopted for the subject device.

H. Conclusions

Based on the indications for use, technological characteristics, performance testing, and comparison to predicate devices, the subject *Archon Anterior Cervical Plate System* has been shown to be substantially equivalent to legally marketed predicate devices, and safe and effective for its intended use.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WC66-G609
Silver Spring, MD 20993-0002

NuVasive, Incorporated
Ms. Cynthia Adams
Regulatory Affairs Associate
7475 Lusk Boulevard
San Diego, California 92121

November 27, 2013

Re: K131025

Trade/Device Name: NuVasive[®] Archon Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: November 6, 2013
Received: November 7, 2013

Dear Ms. Adams:

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

Page 2 – Ms. Cynthia Adams

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours.

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131025

Device Name: NuVasive® Archon Anterior Cervical Plate System

Indications For Use:

The *NuVasive Archon Anterior Cervical Plate System* is intended for anterior screw fixation of the cervical spine. These implants have been designed to provide stabilization as an adjunct to cervical fusion.

Indications for the use of the implant system include degenerative disc disease defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma, spinal stenosis, deformity, tumor, pseudarthrosis or failed previous fusion. Additionally, the three-hole version of the implant system may be appropriate only for patients with large vertebral bodies, and is particularly suited for use following corpectomies for the treatment of tumors and burst fractures.

WARNING: The *NuVasive Archon Anterior Cervical Plate System* is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Prescription Use
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices