NuVasive, Incorporated
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive
Suite 510k
SAINT PAUL MN 55114

September 26, 2019

Re: K192435
Trade/Device Name: NuVasive® NuvaLine®
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: September 3, 2019
Received: September 5, 2019

Dear Mr. Job:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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)*

K192435

Device Name
NuVasive® NuvaLine®

Indications for Use *(Describe)*

NuVasive NuvaLine is a medical device software application intended to assist healthcare professionals in capturing, viewing, measuring, and storage and distribution of spinal alignment assessment images at various time points in patient care. Online synchronization of the database allows healthcare professionals and service providers to conveniently perform and review spinal alignment assessments of images by featuring measurement tools on various platforms. Clinical judgment and experience are required to properly use the software.

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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*"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:

Manthan Damani
Lead Regulatory Affairs Specialist
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 909-1800
Date Prepared: September 25, 2019

### B. Device Name

| | |
|---|---|
| Trade or Proprietary Name: | *NuVasive® NuvaLine®* |
| Common or Usual Name: | Picture archiving and communications system |
| Classification Name: | Picture archiving and communications system |
| Device Class: | Class II |
| Classification: | §892.2050 |
| Product Code: | LLZ |

### C. Predicate Devices

The subject *NuVasive NuvaLine* is substantially equivalent to the primary predicate *NuVasive NuvaLine Mobile App* (K162647) and additional reference devices *NuVasive NVM5 System* (K152942), *Nemaris Surgimap 2.0* (K141669), and *NucleusHealth Nucleus Image Mangement System* (K171130).

### D. Device Description

*NuVasive NuvaLine* is a medical device software application used to calculate the spinal pelvic, lumbar, thoracic, and cervical parameters for pre-operative, intra-operative and post-operative assessment of spinal x-ray images. These measured parameters provide a quantifiable way to assess a patient's spinal deformity and correction correlated to health related quality of life (HRQOL) scores.

The purpose of this premarket notification is to gain clearance of the previously cleared *NuvaLine* app to communicate with cloud server for online synchronization of database to transfer and store assessment data to allow for use of the *NuvaLine* app on different platforms (e.g.: mobile, web interface, desktop) by healthcare professionals and service providers.

*NuVasive NuvaLine* is designed per recommendations provided in the following FDA guidance documents:

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- Off-The-Shelf Software Use in Medical Devices

- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices

## E. Indications for Use

*NuVasive NuvaLine* is a medical device software application intended to assist healthcare professionals in capturing, viewing, measuring, and storage and distribution of spinal alignment assessment images at various time points in patient care. Online synchronization of the database allows healthcare professionals and service providers to conveniently perform and review spinal alignment assessments of images by featuring measurement tools on various platforms. Clinical judgment and experience are required to properly use the software.

## F. Technological Characteristics

As was established in this submission, the subject *NuvaLine* 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 equivalent technological characteristics to its predicate device through comparison in areas including design, intended use, and functions.

**Table 1 – Comparison of Technical Characteristics**

| Specification / Property | Predicate Device | Reference Device | | Subject Device | Discussion |
|---|---|---|---|---|---|
| | **NuVasive NuvaLine Mobile App (K162647)** | **NucleusHealth Nucleus Image Management System (K171130)** | **Nemaris Surgimap 2.0 (K141669)** | **NuVasive NuvaLine** | |
| Intended Use / Indications for Use | The NuVasive NuvaLine Mobile App is a medical device software mobile application intended to assist healthcare professionals in capturing, measuring, and storing spinal alignment assessment images at various time points in patient care. The device allows the healthcare professional to conveniently perform and review spinal alignment assessments of images by featuring measurement tools on their mobile device. | The Nucleus Image Management System (Nucleus IMS) is a software based PACS, to be used by radiologists and other medical personnel. The Nucleus IMS is comprised of software modules that provide image receipt, diagnostic viewing, storage, distribution, enhancement, sharing, manipulation, and networking of medical 2D/3D images at distributed locations. All modules of the Nucleus IMS are web-based and can operate on off-the-shelf hardware, as needed. The Nucleus IMS consists of the following primary components: Nucleus Viewer with image streaming technology for use by medical professionals for diagnostic and clinical image review—Nucleus Image Exchange (iX) for image acceptance, transfer, and sharing with hospitals/clinics as well as between facilities—and Nucleus Image Store for secure cloud based image storage and management through HIPAA compliant encryption. Nucleus iX integrates with the Nucleus Viewer and Nucleus Image Store. Nucleus.io, a web based class I PaaS device, provides the basis for the system and for vendor neutral applications.<br>The Nucleus IMS interfaces with health information systems (HIS) using industry-standard image transfer and data exchange protocols—such as DICOM, HL7, and HTML—through web-based networked gateways and local and wide area networks. The Nucleus IMS is compatible with modalities including: Computed Tomography (CT), Magnetic Resonance Imaging (MR), Ultrasound (US), Computed Radiography (CR), Digital Radiography (DX), Nuclear | The Surgimap software assists healthcare professionals in viewing, storing, and measuring images as well as planning orthopedic surgeries. The device allows service providers to perform generic as well as specialty measurements of the images, and to plan surgical procedures. The device also includes tools for measuring anatomical components for placement of surgical implants, and offer online synchronization of the database with the possibility to share data among Surgimap users. Clinical judgment and experience are required to properly use the software. | NuVasive NuvaLine is a medical device software application intended to assist healthcare professionals in capturing, viewing, measuring, and storage and distribution of spinal alignment assessment images at various time points in patient care. Online synchronization of the database allows healthcare professionals and service providers to conveniently perform and review spinal alignment assessments of images by featuring measurement tools on various platforms. Clinical judgment and experience are required to properly use the software. | Same |

| Specification / Property | Predicate Device | Reference Device | | Subject Device | Discussion |
|---|---|---|---|---|---|
| | **NuVasive NuvaLine Mobile App (K162647)** | **NucleusHealth Nucleus Image Management System (K171130)** | **Nemaris Surgimap 2.0 (K141669)** | **NuVasive NuvaLine** | |
| | | Medicine (NM), Positron Emission Tomography (PT), and X-Ray Angiography (XA). When appropriate, the Nucleus IMS provides and installs software and, optionally, server hardware at client facilities to facilitate secure, web-based connections for image transmission to and from hospital central servers via the Internet. Additionally, industry standard HTTPS, VPNs, and other encryption methodologies are utilized to allow for optimal, secure, rapid streaming of images. Lossless image compression and encryption adhere to standard industry protocols. The Nucleus IMS can be used as a full featured PACS or as an independent viewer in clinical settings.<br><br>Nucleus Image Management System is not intended for display of mammography imaging for diagnosis. | | | |
| Device Class | II | II | II | II | Same |
| Product Code | LLZ | LLZ | LLZ | LLZ | Same |
| Regulation Number (21CFR) | 21 CFR 892.2050 | 21 CFR 892.2050 | 21 CFR 892.2050 | 21 CFR 892.2050 | Same |
| Device Classification Name | Picture archiving and communications system | Picture archiving and communications system | Picture archiving and communications system | Picture archiving and communications system | Same |
| Software Functionalities/ Modalities | Spinal alignment assessments of images | PACS image transfer, sharing, storage, management | Spinal alignment assessments of images | Spinal alignment assessments of images | Same |

| **Specification / Property** | **Predicate Device** | **Reference Device** | | **Subject Device** | **Discussion** |
|---|---|---|---|---|---|
| | **NuVasive NuvaLine Mobile App (K162647)** | **NucleusHealth Nucleus Image Management System (K171130)** | **Nemaris Surgimap 2.0 (K141669)** | **NuVasive NuvaLine** | |
| Algorithms | Various spinal assessment algorithms | N/A | Various spinal assessment algorithms | Various spinal assessment algorithms | Same |
| User Interface | Mobile device | PC or mobile device or web interface | PC or mobile device | PC or mobile device or web interface | Same |
| Obtaining an image | Mobile Device Camera | N/A | Transferred from other devices | Transferred from PACS | Same |
| Online synchronization of database | N/A | N/A | Yes | Yes | Same |
| PACS connectivity | N/A | Yes | Yes | Yes | Same |
| DICOM | N/A | Yes | Yes | Yes (DICOM images from PACS converted to jpeg for use in NuvaLine) | Same |
| Supported Platforms | Mobile application supported on devices running iOS version 10.0 or later. | N/A | N/A | Mobile application supported on devices running iOS version 10.0 or later.<br><br>Web client is supported for the following minimum system specifications:<br>• Windows 10<br>• 3GHz processor<br>• 18GB RAM<br>• Modern browser supporting HTML5.2 and JavaScript ES7 or better.<br>• 1920x1200 display resolution | Same |

| Specification / Property | Predicate Device | Reference Device | | Subject Device | Discussion |
|---|---|---|---|---|---|
| | **NuVasive NuvaLine Mobile App (K162647)** | **NucleusHealth Nucleus Image Management System (K171130)** | **Nemaris Surgimap 2.0 (K141669)** | **NuVasive NuvaLine** | |
| Measurement accuracy | NuvaLine measures angles within ± 3° and offsets within ± 2 cm accuracy. | N/A | N/A | NuvaLine measures angles within ± 3° and offsets within ± 1 cm accuracy. | Same |

*****An additional reference device, NuVasive NVM5 System (K152942) is being introduced to reintroduce SVA and TPA measurements to the subject device.

## G. Performance Data

Nonclinical testing was performed to demonstrate that the subject *NuVasive NuvaLine* is substantially equivalent to other predicate devices and to verify that *NuVasive NuvaLine* meets design specifications and performance characteristics, based upon the intended use.

*NuVasive NuvaLine* was subjected to Verification and Validation Testing according to the Software Requirements Specifications defined for the system. The following testing was performed:

- NuvaLine Cloud Connectivity Validation
- NuvaLine Web Client Cloud Connectivity Validation
- NuvaLine Cloud Connectivity Measurement Library Verification

## H. Conclusions

Based on the indications for use, technological characteristics, performance testing, and comparison to predicate devices, the subject *NuVasive NuvaLine* has been shown to be substantially equivalent to legally marketed predicate device.