DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 1, 2017

NuVasive, Incorporated
% Ms. Olga Lewis
Senior Manager, Regulatory Affairs
7475 Lusk Blvd.
SAN DIEGO CA 92121

Re: K162647
Trade/Device Name: NuVasive® NuvaLine™ Mobile App
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 7, 2017
Received: April 10, 2017

Dear Ms. Lewis:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education 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 Industry and Consumer Education 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,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*

K162647

Device Name
NuVasive® NuvaLine™ Mobile App

Indications for Use *(Describe)*
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.

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.

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:

Olga Lewis
Senior Manager, Regulatory Affairs
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 909-1800
Date Prepared: April 7, 2017

B. Device Name

Trade or Proprietary Name:	*NuVasive® NuvaLine™ Mobile App*
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 Mobile App* is substantially equivalent to the primary predicate *Nemaris Surgimap 2.0* K141669 and the reference predicate *NuVasive NVM5 System* K152942.

D. Device Description

The *NuVasive NuvaLine Mobile App* is a medical device software used to measure spinal pelvic and cervical parameters from an image of patient's x-rays taken with the device's camera. 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.

E. 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.

F. Technological Characteristics

As was established in this submission, the subject *NuvaLine Mobile App* 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		Subject Device	Discussion
	NuVasive NVM5 System (K152942)	**Nemaris Surgimap 2.0 (K141669)**	**NuVasive NuvaLine Mobile App**	
Intended Use / Indications for Use	The NVM5® System is a medical device that is intended for intraoperative neurophysiologic monitoring during spinal surgery. The device provides information directly to the surgeon, to help assess a patient's neurophysiologic status. NVM5 provides this information by electrically stimulating nerves via electrodes located on surgical accessories and monitoring electromyography (EMG), transcranial or lumbar motor evoked potential (MEP) or somatosensory evoked potential (SSEP) responses of nerves. The System also integrates Bendini™ software used to locate spinal implant instrumentation for the placement of spinal rods.	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.	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.	Same
Device Classification Name	Surgical nerve stimulatory/locator; Evoked response electrical stimulator; Neurological stereotaxic instrument; Electromyography (EMG) monitor/stimulator	Picture archiving and communications system	Picture archiving and communications system	Same
Software Functionalities/ Modalities	For NuvaLine - spinal alignment assessments of images	Spinal alignment assessments of images	Spinal alignment assessments of images	Same

Specification/ Property	Predicate Device		Subject Device	Discussion
	NuVasive NVM5 System (K152942)	**Nemaris Surgimap 2.0 (K141669)**	**NuVasive NuvaLine Mobile App**	
Algorithms	Lumbar Algorithm (PT, PI-LL, SVA) Cervical Algorithm (TPA, TS-CL, CSVA)	Various	Lumbar Algorithm (PT, PI-LL, SVA) Cervical Algorithm (TPA, TS-CL, CSVA)	Same
User Interface	NuVasive-supplied computer with optional touch screen and/or keyboard/mouse Mobile device (for NuvaLine only)	PC or mobile device	Mobile device	Same
Obtaining an image	Mobile Device Camera	Transferred from other devices	Mobile Device Camera	Same
DICOM	N/A	Yes	N/A	Same

G. Performance Data

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

The *NuvaLine Mobile App* was subjected to Verification and Validation Testing according to the Software Requirements Specifications defined for the system. Verification testing was performed to confirm that NuvaLine accurately measures angles and offsets based off of x-ray images, and that these values are displayed properly with correct color-coded alert indications. Angle measurements were verified within ± 3° while offset measurement were verified within ± 2 cm accuracy. Verification activities also included testing specific to positioning of the camera and reproducibility.

Validation testing was performed to confirm that the graphical user interface (GUI) and device components function as intended.

H. Conclusions

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