October 29, 2021

Alphatec Spine, Inc.
David Gramse
Sr. Director, Regulatory Affairs
1950 Camino Vida Roble
CARLSBAD CA 92008

Re: K211987
Trade/Device Name: ATEC Alignment App
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management and Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: September 30, 2021
Received: October 1, 2021

Dear David Gramse:

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 and Part 809); 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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211987

Device Name
ATEC Alignment App

Indications for Use *(Describe)*
The ATEC Alignment App assists healthcare professionals in viewing, measuring, and storing images as well as planning orthopedic surgeries. The app allows the healthcare professional to perform generic and specialty measurements of the images, and to plan surgical procedures. The app includes tools for measuring anatomical components for implant selection, and offers the possibility to share data among ATEC Alignment App users. The app is for planning use only and is not intended for primary diagnostic use.

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.

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510(k) Summary of Safety and Effectiveness

(21 CFR 807.92)

I. SUBMITTER:

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Contact Person: David Gramse
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Date Summary Prepared: June 25, 2021

II. DEVICE

Name of Device:	ATEC Alignment App
510(k) Number:	K211987
Common or Usual Name:	Medical Image Management and Processing System
Classification Name:	Medical Image Management and Processing System (21 CFR 892.2050)
Regulatory Class:	Class II
Product Code:	LLZ

III. LEGALLY MARKETED PREDICATE DEVICES

510(k)	Product Code	Trade Name	Manufacturer
Primary Predicate Device			
K141669	LLZ	Surgimap 2.0	Nemaris, Inc.
Additional Predicate Device			
K162647	LLZ	NuVasive NuvaLine Mobile App	NuVasive, Inc.

IV. DEVICE DESCRIPTION

The ATEC Alignment App is intended for use by trained healthcare professionals as a standalone software for viewing, measuring, and storing of x-ray images. The app is a medical device software used to measure spinopelvic parameters from patient x-rays images 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 based on published literature. Clinical judgment and experience are required to properly use the software.

V. INDICATIONS FOR USE

The ATEC Alignment App assists healthcare professionals in viewing, measuring, and storing images as well as planning orthopedic surgeries. The app allows the healthcare professional to perform generic and specialty measurements of the images, and to plan surgical procedures. The app includes tools for measuring anatomical components for implant selection, and offers the possibility to share data among ATEC Alignment App users. The app is for planning use only and is not intended for primary diagnostic use.

VI. TECHNOLOGICAL COMPARISON TO PREDICATES

The technological design features of the subject ATEC Alignment App were compared to the predicates in intended use, indications for use, design, function and technology and it was demonstrated that they are substantially equivalent.

Characteristic	Predicate Devices		Subject Device	Discussion
	Nemaris Surgimap 2.0 (K141669)	**NuVasive NuvaLine Mobile App (K162647)**	**ATEC Alignment App (K211987)**	
Indications for Use	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.	The ATEC Alignment App assists healthcare professionals in viewing, measuring, and storing images as well as planning orthopedic surgeries. The device allows the healthcare professional to perform generic and specialty measurements of the images, and to plan surgical procedures. The device offers the possibility to share data among ATEC Alignment App users.	Similar to Surgimap – the only difference is that the subject device does not include tools for measuring anatomical components for implant selection. This difference does not affect substantial equivalence to the predicate. Same as NuvaLine

Regulatory Class/Code	Class II LLZ (21 CFR 892.2050)	Class II LLZ (21 CFR 892.2050)	Class II LLZ (21 CFR 892.2050)	Same
Device Classification Name	Medical Image Management and Processing System	Medical Image Management and Processing System	Medical Image Management and Processing System	Same
Operating System	PC: Windows + MAC Mobile: Android + iOS	Mobile: Android + iOS	Mobile: Android + iOS	Similar to Surgimap – the subject device is limited to use on mobile phones (iOS and Android). This difference does not affect substantial equivalence to the predicate. Same as NuvaLine
Software Functionalities / Modalities	Spinal alignment assessments of images	Spinal alignment assessments of images	Spinal alignment assessments of images	Similar
Provides Normative Values for Measurement Comparison	Yes	Yes	Yes	Same
Includes user-defined circles for anatomical location of femoral head for sagittal measurements	Yes	Yes	Yes	Same
Includes user-defined lines for identification of endplates for sagittal and coronal measurements	Yes	Yes	Yes	Same
Provides color-coded measurement results to display variance from the defined norm	Yes	Yes	Yes	Same
Algorithms	Patient parameters and calculations based on published literature	Lumbar Algorithm (PT, PI-LL, SVA) Cervical Algorithm (TPA, TS-CL, CSVA)	Patient parameters and calculations based on published literature	Same
User Interface	PC or mobile device	Mobile device	Mobile device	Similar to Surgimap – the subject device is limited to use on

				mobile phones (iOS and Android). This difference does not affect substantial equivalence to the predicate. Same as NuvaLine
Obtaining an image	Transferred from other devices, or mobile device camera	Mobile Device Camera	Transferred from other devices, or mobile device camera	Same
Sharing an image	Email	None	Email/QR Code	Same
Human Intervention for interpretation and manipulation of images	Required	Required	Required	Same
Control of life-saving devices	None	None	None	Same

VII. PERFORMANCE DATA

The ATEC Alignment App was subjected to verification and validation testing in accordance with the functional requirements. Performance testing confirmed that the app accurately measures angles from x-ray images, and that resultant values are displayed properly with correct color-coded range. Angle measurements were verified within ± 2° accuracy. Validation testing was performed to confirm that the graphical user interface (GUI) and that data system features function as intended. A direct comparison test between the ATEC Alignment App and the Surgimap device using the same clinically representative images was conducted which concluded that the performance between the two devices was similar.

The results demonstrate that the subject ATEC Alignment App is substantially equivalent to Surgimap 2.0 (K141669) and the NuvaLine Mobile App (K162647) and verifies that the subject device meets design specifications and performance characteristics based upon its intended use.

Clinical Information

Not applicable; determination of substantial equivalence is not based on an assessment of clinical performance data.

VIII. CONCLUSION

Based upon the information provided in this 510(k) submission, it has been determined that the subject device is substantially equivalent to the legally marketed primary predicate

device (Surgimap 2.0, K141669) based on intended use, design, functionality, performance testing and other key technological characteristics.