November 15, 2023

NSite, Inc.
Michael Gardner, MD
Co-Founder & CEO
821 Stanford Ave.
Menlo Park, California 94025

Re: K230463
Trade/Device Name: NSite Scoliosis Assessment App
Regulatory Class: Unclassified
Product Code: LDK
Dated: October 16, 2023
Received: October 17, 2023

Dear Dr. Gardner:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Tushar Bansal -S

for Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Rehabilitation Devices
OHT5: Office of Neurological
and Physical Medicine Devices
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)*
K230463

Device Name
NSite Scoliosis Assessment App

Indications for Use *(Describe)*
The NSite Scoliosis Assessment App is intended as an adjunct tool for qualified healthcare professionals to provide deformity measurements and guide management recommendations based on a calculated Asymmetry Index for patients with or at risk for idiopathic scoliosis, which will yield an output of low or high risk of clinically significant scoliosis, which is defined as a Cobb Angle greater than 20 degrees.

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.

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510(k) Summary

Date Prepared: November 14, 2023

Submitter: NSite, Inc.
821 Stanford Ave.
Menlo Park, CA 94025

Contact: Michael J. Gardner, MD
Co-Founder & CEO
NSite, Inc.
917-584-6909
mike@nsitemedical.com

Proprietary Name: NSite Scoliosis Assessment App

Common Name: Optical Contour Sensing Device

Classification: Unclassified, Pre-Amendment
Product Code: LDK

Review Panel: Physical Medicine

Substantially Equivalent Device: K923792 – Quantec Image Processing Ltd. Quantec Spinal Measurement System

Device Description:

NSite Medical leverages 3D scanning on a mobile device for scoliosis screening and monitoring. NSite's proprietary algorithm calculates the risk of having clinically significant scoliosis that may require treatment by a specialist.

The NSite Scoliosis Assessment App generates a 3D scan of the individual using a mobile device camera. Using the 3D scan, the application analyzes the asymmetry of the individual's back surface and calculates an Asymmetry Index (AI). The Asymmetry Index is a quantitative measure of the back asymmetry. The Asymmetry Index is then used to calculate a high/low risk stratification that a patient will have clinically significant

scoliosis (defined as Cobb angle > 20 degrees) using a logistic regression model. This risk stratification, when considered in combination with the stated NSite Scoliosis Assessment App performance, is intended to provide health care providers with information that can be used for management recommendations. The model was developed using a database of patient Asymmetry Indexes with known Cobb angles.

Indications for Use:

The NSite Scoliosis Assessment App is intended as an adjunct tool for qualified healthcare professionals to provide deformity measurements and guide management recommendations based on a calculated Asymmetry Index for patients with or at risk for idiopathic scoliosis, which will yield an output of low or high risk of clinically significant scoliosis, which is defined as a Cobb Angle greater than 20 degrees.

Comparison of Technological Characteristics:

The proposed NSite Scoliosis Assessment App and its predicate device, Quantec Spinal Measurement System (K923792), are similar with regards to their intended use, clinical indications, principle of operation and fundamental technology. In conclusion, NSite, Inc. believes that the NSite Scoliosis Assessment App does not introduce any new potential safety and/or effectiveness issues and is comparable to the identified predicate device, Quantec Spinal Measurement System (K923792).

Characteristic	**Proposed Device** NSite, Inc. NSite Scoliosis Assessment App (K230463)	**Predicate Device** Quantec Image Processing Ltd. Quantec Spinal Measurement System (K923792)	**Similarities and Differences**
Classification	Unclassified	Unclassified	Identical
Regulation	Unclassified	Unclassified	Identical
Product Code	LDK	LDK	Identical
Prescription	Yes	No	Difference – Both devices are intended to

Characteristic	Proposed Device NSite, Inc. NSite Scoliosis Assessment App (K230463)	Predicate Device Quantec Image Processing Ltd. Quantec Spinal Measurement System (K923792)	Similarities and Differences
			be used by health care professionals. The restriction to use the proposed NSite Scoliosis Assessment App by prescription only does not raise new questions of safety and effectiveness.
Indications for Use	The NSite Scoliosis Assessment App is intended as an adjunct tool for qualified healthcare professionals to provide deformity measurements and guide management recommendations based on a calculated Asymmetry Index for patients with or at risk for idiopathic scoliosis, which will yield an output of low or high risk of clinically significant scoliosis, which is defined as a Cobb Angle greater than 20 degrees.	Quantec Spinal Measurement System is indicated as an optical contour sensing device to provide topographical images for the 3D assessment of back asymmetries.	Similar Both devices are intended to be used by health care professionals. Both devices are optical sensing devices intended to generate 3D surface images of a patient's back and trunk and quantify surface alignment and deformity parameters.
Patient Population	Child / Adolescent age 10-18	Adult or pediatric populations	Similar – Both devices include pediatric patients in their intended use.

Characteristic	**Proposed Device** NSite, Inc. NSite Scoliosis Assessment App (K230463)	**Predicate Device** Quantec Image Processing Ltd. Quantec Spinal Measurement System (K923792)	**Similarities and Differences**
Intended Users	Health care medical professionals, such as primary care providers, pediatricians, orthopaedic surgeons, physical therapists, orthotists, school nurses, and chiropractors.	Health specialists such as podiatrists, pedorthists, orthopedist, physiotherapists, chiropractors, osteopaths, and kinesiotherapists.	Similar – Both devices are intended to be used by health care professionals.
Environment	Health care facilities	Health care facilities	Identical
Technique	Surface Topography – structured light projection	Surface Topography – structured light projection	Identical
Method	Non-Tactile	Non-Tactile	Identical
Measurement	Static	Static	Identical
Principle of Operation	Based upon TrueDepth vertical-cavity surface-emitting laser (VCSEL) technology scanning technology, the image is obtained with iOS mobile device camera.	Based upon digital photogrammetry	Similar – Both devices utilize digital cameras to obtain patient images
Hardware Component	None – The NSite Scoliosis Assessment App is a software only device. The minimum mobile device hardware requirements are defined in the IFU.	Digital Camera; Quartz halogen light Booth	Similar – Both devices operate on compatible hardware, the NSite Scoliosis Assessment App is installed on user supplied hardware.
Software	Software provides user interface to acquire images, identify regions of interest, perform asymmetry calculations, report asymmetry results and patient scan images.	Software to control the camera, measure the 3D trunk images and to record and quantify deformities (3D assessment)	Similar – Both devices utilize software to analyze images and report deformity values.

Characteristic	Proposed Device NSite, Inc. NSite Scoliosis Assessment App (K230463)	Predicate Device Quantec Image Processing Ltd. Quantec Spinal Measurement System (K923792)	Similarities and Differences
Use of Body Markers	No	Yes	Difference – The proposed device is manually segmented. Once the 3D mesh is annotated, the scan points are automatically measured and the Asymmetry Index and heat map is calculated and reported. The predicate device features body markers the user places in specified locations to help identify and reference anatomical landmarks in the photographs. The annotation method and proposed device results have been demonstrated to perform substantially equivalent to the predicate device method.

The general intended use and technology are equivalent between the predicate and the NSite Scoliosis Assessment App. The predicate device is not limited to use by prescription, whereby the proposed NSite Scoliosis Assessment App in intended to be used by prescription only. Further, the NSite Scoliosis Assessment App is intended to be used by healthcare professionals. The restriction to the use of the proposed NSite Scoliosis Assessment App does not raise new questions of safety and effectiveness. The difference in technology is that the predicate quantifies related alignment and deformity parameters that corresponds to given anatomical markers placed by the user, whereas the NSite Scoliosis Assessment App quantifies surface alignment and deformity parameters that correspond to manually segmented regions of interest (ROIs). The method was found to be appropriate and reproducible for its intended use per a clinical study.

Non-Clinical Testing Summary:

The following design control, risk management and quality assurance methodologies were utilized to develop the NSite Scoliosis Assessment App:

- Risk Analysis
- Requirements Review
- Design Reviews
- Testing on Unit Level (Verification)
- Integration Testing (System Verification)
- Performance Testing (V&V)
- Safety Testing (V&V)
- Simulated Use Testing (Validation)

Software documentation for Moderate Level of Concern software per the FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", issued on May 11, 2005, was established and maintained for the NSite Scoliosis Assessment App. The NSite Scoliosis Assessment App was tested in accordance with NSite's verification and validation procedures.

All predefined acceptance criteria for the performance testing were met. The results from the performance testing executed on the NSite Scoliosis Assessment App produced results consistently according to its intended use.

Clinical Testing Summary:

A clinical study of the NSite Scoliosis Assessment App was conducted to assess the reproducibility and reliability of the scanning functionality and validate the accuracy of the predicated probability of major Cobb angle as compared to a Cobb angle obtained via radiograph. The clinical study was performed using adolescent patients spanning the age range where Adolescent Idiopathic Scoliosis (AIS) commonly presents and remains treatable. The clinical study was performed using adolescents of gender and race at ratios where AIS is commonly observed. The clinical study demonstrated that the NSite Scoliosis Assessment App is safe and effective for its intended use, substantially equivalent to the currently cleared predicate device (K923792), and raises no new questions of safety and effectiveness.

Conclusions Drawn from Non-Clinical and Clinical Tests:

The subject device and the predicate devices are substantially equivalent, with respect to intended use, design features, technological characteristics, performance, and safety and effectiveness. The subject device is substantially equivalent to the predicate device, K923792.

Conclusion:

The non-clinical and clinical software testing performed on the NSite Scoliosis Assessment App demonstrates that the NSite Scoliosis Assessment App performs according to its intended use. NSite, Inc. considers the NSite Scoliosis Assessment App (subject device) to be similar to the legally marketed predicate device, K923792, and is as safe and effective as the predicate device without raising any new safety and/or effectiveness concerns.