October 7, 2024

Verdure Imaging
Christopher Schlenger
President, Verdure Imaging
4560 N. Pershing Ave., Ste. A
Stockton, California 95219

Re: K241029
Trade/Device Name: SpineUs™ System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: IYO, ITX, QIH
Dated: September 5, 2024
Received: September 6, 2024

Dear Christopher Schlenger:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Yanna S. Kang -S

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological
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OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241029

Device Name

SpineUs™ System

Indications for Use *(Describe)*

The SpineUs™ system is a software-based, tracked, ultrasound imaging system and accessories, intended for diagnostic imaging. It is indicated for diagnostic ultrasound imaging in the following applications: musculoskeletal (conventional, superficial). The system is intended for use by trained chiropractors and radiologists in a hospital or medical clinic.

The SpineUs™ system is intended for assisting trained chiropractors and radiologists in acquiring, viewing, and measuring ultrasound images of the spine in both clinic and hospital settings. The SpineUs™ system is intended to be used as an adjunct to conventional imaging method that allows trained chiropractors and radiologists to measure spine-related anatomical components on images (e.g., intervertebral angles and spine curvature). The system also allows the review and management of patient measurement data. Clinical judgment of anatomy and experience are required to properly use the SpineUs™ system.

Patient management decisions should not be made based solely on the results of the SpineUs™ computer application. The user shall retain the ultimate responsibility of ascertaining the measurements based on standard practices and clinical judgement.

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.

510(k) Summary Prepared October 4th, 2024 **K241029**

Sponsor: Verdure Imaging, Inc.
4560 N. Pershing Ave. Ste. A
Stockton, CA 95219

Contact Person: Christopher Schlenger

Device name: SpineUs™ System

Common Name: Ultrasonic imaging system; Diagnostic ultrasonic transducer

Trade Name: SpineUs™ system

Classification:
Regulatory Class: II
Regulatory Category: 21CFR 892.1560, 892.1570, and 892.2050 (IYO, ITX, QIH)
Classification Panel: Radiology

A. Legally Marketed Predicate Devices

The predicate device is the LOGIQ E10 (K231966), manufactured by GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC**.**

B. Device Description:

The SpineUs™ System is a diagnostic ultrasound system, which consists of the FDA cleared Clarius Ultrasound Scanner C3 HD3 (K213436), a consumer PC, a tracking system with OptiTrack cameras connected to a POE switch and active LED markers, and the SpineUs™ computer application.

The SpineUs™ computer application, installed in the consumer PC, processes the ultrasound imaging data received from the Clarius Ultrasound Scanner and the tracking data received from the tracking system. The SpineUs™ computer application allows the operator to view ultrasound images of the spine, segment the ultrasound images using artificial intelligence, generate and visualize 3D reconstructions of the surface of the spine in real-time, measure spine-related anatomical components (e.g., intervertebral angles and spine curvature), review and manage patient measurement data, and generate and export printable reports.

The SpineUs™ system comprises the following:

Transducer / Scanner	Clarius Ultrasound Scanner, model C3 HD3 (K213436)
Software	SpineUs™ computer application
Tracking system	Motive Software OptiTrack Cameras SpineUs™ Active LED Markers Power over Ethernet (PoE) switch

Accessories	USB-C charging cables USB-C charging block Wall mounted camera holders/covers Tracker Reference (includes belt) Consumer PC

C. Intended Use / Indications for Use

The SpineUs™ system is a software-based, tracked, ultrasound imaging system and accessories, intended for diagnostic imaging. It is indicated for diagnostic ultrasound imaging in the following applications: musculoskeletal (conventional, superficial). The system is intended for use by trained chiropractors and radiologists in a hospital or medical clinic.

The SpineUs™ system is intended for assisting trained chiropractors and radiologists in acquiring, viewing, and measuring ultrasound images of the spine in both clinic and hospital settings. The SpineUs™ system is intended to be used as an adjunct to conventional imaging method that allows trained chiropractors and radiologists to measure spine-related anatomical components on images (e.g., intervertebral angles and spine curvature). The system also allows the review and management of patient measurement data. Clinical judgment of anatomy and experience are required to properly use the SpineUs™ system.

Patient management decisions should not be made based solely on the results of the SpineUs™ system. The user shall retain the ultimate responsibility of ascertaining the measurements based on standard practices and clinical judgement.

D. Comparison of the Subject Device and Predicate Device for Demonstration of Substantial Equivalence

Criteria	Subject Device	Predicate Device
	SpineUs™ system	**LOGIQ E10**
510(k) Holder/ Manufacturer	Verdure Imaging, Inc.	GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC.
Submission Reference	Current Submission	K231966
Regulatory Class	Class II	Class II
Product code(s)	IYO (primary), ITX, QIH	IYN (primary), IYO, ITX
Regulation number	21 CFR 892.1560 21 CFR 892.1570 21 CFR 892.2050	21 CFR 892.1550 21 CFR 892.1560 21 CFR 892.1570
Regulation name	Ultrasonic Pulsed Echo Imaging System Diagnostic Ultrasonic Transducer Medical image management and processing system	Ultrasonic Pulsed Doppler Imaging System Ultrasonic Pulsed Echo Imaging System Diagnostic Ultrasonic Transducer
Transducer Models	Clarius C3 HD3 (FDA cleared, K213436)	Various
Transducer Types	Convex Array	Convex Array Linear Array

		Phased Array Intracavity
Intended Use	Diagnostic ultrasound imaging of the spinal region of the human body	Diagnostic ultrasound imaging and fluid flow analysis of the human body
Indications for Use and Clinical Usage	The SpineUs™ system is a software-based, tracked, ultrasound imaging system and accessories, intended for diagnostic imaging. It is indicated for diagnostic ultrasound imaging in the following applications: musculoskeletal (conventional, superficial). The system is intended for use by trained chiropractors and radiologists in a hospital or medical clinic. The SpineUs™ system is intended for assisting trained chiropractors and radiologists in acquiring, viewing, and measuring ultrasound images of the spine in both clinic and hospital settings. The SpineUs™ system is intended to be used as an adjunct to conventional imaging method that allows trained chiropractors and radiologists to measure spine-related anatomical components on images (e.g., intervertebral angles and spine curvature). The system also allows the review and management of patient measurement data. Clinical judgment of anatomy and experience are required to properly use the SpineUs™ system. Patient management decisions should not be made based solely on the results of the SpineUs™ computer application. The user shall retain the ultimate responsibility of ascertaining the measurements based on standard practices and clinical judgement.	LOGIQ E10 is intended for use by a qualified physician in a hospital or medical clinic, for ultrasound evaluation of: • Fetal / Obstetrics • Abdominal (including Renal, Gynecology/Pelvic) • Pediatric • Small Organ (Breast, Testes, Thyroid) • Neonatal Cephalic • Adult Cephalic • Cardiac (Adult and Pediatric) • Peripheral Vascular • Musculoskeletal Conventional and Superficial • Urology (including Prostate) • Transrectal • Transvaginal • Transesophageal and Intraoperative (Abdominal and Vascular)
Tracking technology	3D Optical tracking using GPS-like technology	2D/3D GPS tracking using GPS-like technology.
Artificial intelligence (AI) technology	AI-based segmentation of vertebral bone tissue in ultrasound image frames.	AI-based tools such as Breast Assistant and Auto Lesion Segmentation powered by Koios DS™, Auto Doppler Assistant, and OB Measurement Assistant.
Display	Consumer PC, provided by Verdure Imaging, Inc.	Mobile console approximately 585 mm wide (keyboard), 991 mm deep and 1300 mm high that provides digital acquisition, processing, and display capability. The user interface includes a computer keyboard, specialized controls, 12-inch-high resolution color touch screen and 23.8-inch High Contrast LED LCD monitor
Modes of Operation	B-mode	B, M, PW Doppler, CW Doppler, Color Doppler, Color M Doppler, Power Doppler, Harmonic Imaging, Coded Pulse, 3D/4D Imaging mode, Elastography, Shear Wave Elastography, Attenuation Imaging and Combined modes: B/M, B/Color, B/PWD, B/Color/PWD, B/Power/PWD

Safety Standards	The SpineUs™ System complies with the following safety standards: IEC 60601-1 IEC 60601-1-2 IEC 60601-2-37 ISO 10993-1 ISO 14971 NEMA PS 3.1 – 3.20	The LOGIQ E10 complies with the following safety standards: IEC 60601-1 IEC 60601-1-2 IEC 60601-2-37 ISO 10993-1 ISO 14971 NEMA PS 3.1 – 3.20

Discussion of Similarities and Differences

Similarities to the Primary Predicate Device

The subject device has the same technological characteristics as the predicate as follows:

1. The Regulatory Class is the same for both devices.
2. The Product codes IYO and ITX are included in the Product codes of the subject and predicate devices.
3. Both devices are indicated to be used with FDA cleared transducers, of Convex Array type.
4. The intended use is the same for both devices: diagnostic ultrasound of the human body.
5. Both devices are intended for use in professional healthcare environments by trained healthcare professionals for ultrasound evaluation of Musculoskeletal (conventional and superficial).
6. Both devices use tracking technology.
7. Both devices use artificial intelligence technology for segmentation of ultrasound imaging frames.
8. Both devices can be used in the B mode of operation.
9. Both devices are compliant with the same safety standards.
10. Both devices have tissue contact materials tested for biocompatibility. The only component with tissue contact material in the SpineUs™ system is the Clarius C3 HD3 (FDA cleared, K213436).

Differences from Primary Predicate Device

1. In general, the subject device has fewer indications for use than the predicate device.
2. The subject device is not indicated for Product code IYN.
3. The predicate device is not indicated for Product code QIH.
4. The subject device is indicated to be used with the transducer model C3 HD3 (FDA cleared, K213436), while the predicate device requires other FDA cleared transducer models.
5. The subject device is indicated to be used only with transducers of Convex Array type, while the predicate device allows the use of additional transducer types.
6. The subject device is indicated to be used only for diagnostic ultrasound imaging of the spinal region of the human body, while the predicate device can be used for diagnostic ultrasound imaging of other regions of the human body and fluid flow analysis.
7. The subject device is indicated to be used only by trained chiropractors and radiologists, while the predicate device can be used by trained healthcare professionals.
8. The subject device is indicated to be used only for ultrasound evaluation of Musculoskeletal (conventional and superficial), while the predicate device allows more uses.
9. The subject device and predicate device use different tracking technologies. The subject device uses Optical tracking with passive LED optical markers, while the predicate device uses 2D/3D GPS tracking using GPS-like technology.
10. The subject device uses artificial intelligence technology only for segmentation of vertebral bone tissue in ultrasound imaging frames, while the predicate device uses artificial intelligence technology for lesion segmentation and other applications.

10. The subject device includes a consumer PC with the required software installed in it, provided by the

manufacturer, while the predicate device includes its own mobile console.

11. The subject device is indicated to be used only in B-Mode, while the predicate device allows additional modes of operation.

Performance Testing for Technology Differences

The differences from the predicate device have been tested to ensure that these differences do not raise new questions of safety and effectiveness. Specifically, the primary differences identified above, such as the tracking technology, have been tested and the data provided in the verification and validation sections of this submission.

E. SpineUs™ Segmentation AI

Data Description - Development Dataset

The Development Data used to train the Segmentation AI is separate from the Non-Clinical and Clinical Testing Datasets. This Development Data included a total of 81 ultrasound image sequences from 45 patients. In total, 17684 images were used in the development dataset. Ultrasound sequences were well distributed between axially- and sagitally-orientated imaging, and thoracic and lumbar regions.

Image-level annotations were performed on a per-frame basis, where a team of trained clinical experts labelled bone surface structures. When available, corresponding thoracic CT imaging served as a ground truth to assist in the annotation process. All annotations were reviewed by a separate annotator. These annotations were used as the ground truth for the Segmentation AI training process.

The Development Data was acquired from a single site using the SpineUs™ system, and included a diverse patient population, as shown in the table below, and illustrates a balanced distribution of sex, age range, body mass index, and ethnicity.

Demographic		Development Data
Gender	**Male (%)**	55.5%
	Female (%)	42.2%
	Unknown (%)	2.3%
Age	**Mean (years)**	51.2
	St. Dev. (years)	16.6
Body Mass Index	**Mean (kg/m^2)**	27.3
	St. Dev. (kg/m^2)	6.5
Ethnicity	**Caucasian or White (%)**	60.0%
	African American or Black (%)	37.7%
	Hispanic / Latino (%)	0.0%
	Other (%)	2.3%

Non-Clinical and Clinical Testing Dataset

Standalone Segmentation AI performance testing was performance to assess the ability of the

Segmentation AI to delineate between bone surfaces and background on ultrasound images from a recorded ultrasound sequence. A set of recorded ultrasound sequences, acquired with the SpineUs™ system, was analyzed by the Segmentation AI, with the outputs annotated by at least two clinical experts, and the results were compared to an established historical control for the Non-Clinical and Clinical Performance Testing. The demographic information of the Testing Datasets is presented in the below table, and encompass a diverse patient population, where all data used in the Testing Datasets is obtained from clinical sites which are independent from those which are included in the Development dataset.

As with the development data, image-level annotations were performed on a per-frame basis, where a team of trained clinical experts labelled bone surface structures. All annotations were reviewed by a separate annotator. These annotations were used as the ground truth for the pixel-based metrics.

Non-Clinical and Clinical Performance Testing Dataset (n = 31)		
	Mean (Years)	**SD (Years)**
Age	23.5	16.2
	Count	**%**
Sex		
Male	13	41.9
Female	18	58.1
Body Mass Index		
< 18.5	8	25.8
18.5 - 24.5	11	35.5
> 24.9	12	38.7
Ethnicity		
Caucasian or White	8	25.8
African American or Black	11	35.5
Hispanic	4	12.9
Asian	5	16.1
Other	3	9.7
Spinal Curvature		
< 20°	20	64.5
20° – 40°	7	22.6
> 40°	4	12.9

Non-Clinical Performance Testing

Segmentation AI Summary of Non-Clinical Endpoints, Success Criteria, and Results

Name	**Description**	**Success Criteria**	**Results**
Average Percentage of Transverse Processes Identified*	The number of transverse processes correctly identified relative to the total real number of transverse processes present in the 3D reconstruction of the spine	> 80 %	100.0% [100.0% - 100.0%]
Average Inference Time	The average time required to process a single 2D ultrasound image frame with the evaluated Segmentation AI	> 25 frames per second	140.05 frames per second

	model		
Pixel-Based Metrics	Various pixel-based metrics which are used to identify relative performance of individual image segmentations (Sensitivity, Specificity, Precision, Dice Coefficient, Balanced Accuracy, 95th Percentile Hausdorff Distance)	N/A	Sensitivity: 41.80%. Specificity: 99.19%. Precision: 38.70%. Dice Coefficient: 0.4019. Balanced accuracy: 70.49%. 95th %ile HD: 12.91 mm.

* Primary Endpoints

Non-Clinical Performance testing was performed on the standalone Testing Dataset, which is separate to the Development Dataset. Breakdowns of performance in each of the patient subgroups are presented in the below table.

Patient Subgroup	**Number of Patients**	**Percentage of transverse processes identified (%)**
All Patients	31	100.0 [100.0 – 100.0] %
Gender		
Male	13	100.0 [100.0 – 100.0] %
Female	18	100.0 [100.0 – 100.0] %
Age		
<18	19 [13.1 ± 2.2]	100.0 [100.0 – 100.0] %
19-50	7 [29.0 ± 7.3]	100.0 [100.0 – 100.0] %
>50	5 [55.6 ± 3.9]	100.0 [100.0 – 100.0] %
Body Mass Index		
<18.5	8 [16.7 ± 1.3]	100.0 [100.0 – 100.0] %
18.5-24.9	11 [21.4 ± 1.4]	100.0 [100.0 – 100.0] %
>25.0	12 [28.7 ± 2.4]	100.0 [100.0 – 100.0] %
Ethnicity		
Caucasian or White	8	100.0 [100.0 – 100.0] %
African American or Black	11	100.0 [100.0 – 100.0] %
Hispanic	4	100.0 [100.0 – 100.0] %
Asian	5	100.0 [100.0 – 100.0] %
Other	3	100.0 [100.0 – 100.0] %
Spinal Curvature		
< 20°	20	100.0 [100.0 – 100.0] %
20° – 40°	7	100.0 [100.0 – 100.0] %
> 40°	4	100.0 [100.0 – 100.0] %

Clinical Performance Testing

Clinical performance testing was performed on the Testing Dataset by three different observers measuring scoliosis angle on the SpineUs^{TM} system images and X-ray images of the same patients. The

absolute value of the difference between the SpineUs™ system and X-ray-based measurements is shown in the table below for each patient subgroup.

Patient Subgroup	Number of Patients	Average error (mm, 95% CI)
All Patients	31	2.81 (2.36, 3.25)
Sex		
Male	13	2.45 (1.99 - 2.92)
Female	18	3.06 (2.35 - 3.76)
Age		
<18	19 [13.1 ± 2.2]	3.00 (1.80 - 3.18)
19-50	7 [29.0 ± 7.3]	2.49 (1.81 - 3.18)
>50	5 [55.6 ± 3.9]	2.54 (1.83 - 3.24)
Body Mass Index		
<18.5	8 [16.7 ± 1.3]	2.87 (1.76 - 3.98)
18.5-24.9	11 [21.4 ± 1.4]	3.04 (1.94 - 4.13)
>25.0	12 [28.7 ± 2.4]	2.55 (1.47 - 3.64)
Ethnicity		
Caucasian or White	8	2.59 (1.97 - 3.21)
African American or Black	11	3.15 (2.11 - 4.20)
Hispanic	4	2.50 (1.81 - 3.19)
Asian	5	2.65 (1.80 - 3.49)
Other	3	2.82 (1.58 - 4.07)
Spinal Curvature		
< 20°	20	2.34 (1.96, 2.71)
20° – 40°	7	2.57 (1.83, 3.31)
> 40°	4	5.57 (3.52, 7.62)

F. Summary of Non-Clinical Performance Testing of the SpineUs™ system

The SpineUs™ system was designed and developed by Verdure Imaging, Inc. in accordance with the applicable requirements and standards to establish performance and safety of the device. The device's safety and performance were verified by tests conducted by Verdure Imaging, Inc and accredited third-party laboratories. Validation testing was performed to ensure that the final product is capable of meeting the requirements for the specified clinical applications and performs as intended to meet users' needs, while demonstrating substantial equivalence to the predicate device.

Non-clinical performance testing of the SpineUs™ system demonstrate compliance to the following standards:

Standard	Title of Standard
IEC 60601-1	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Compatibility – Requirements and tests

IEC 60601-2-37	Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
ISO 10993-1	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISO 14971	Medical Devices – Application of Risk Management to Medical Devices
NEMA PS 3.1 – 3.20	Digital Imaging and Communications in Medicine (DICOM) Set

G. Conclusion & Summary of Substantial Equivalence

Based on the information presented in this premarket notification, and based on the fundamental scientific technology, technological characteristics, intended use, environment of use, and indications for use, the SpineUs™ system has been determined to be substantially equivalent in terms of safety and effectiveness to the predicate device, the Logiq E10 (510(k)-cleared in K231966).

The differences in design between the subject device and the predicate device do not raise any issues related to safety or effectiveness.