JointVue LLC
℅ Mr. Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
SAINT PAUL MN 55114

June 25, 2021

Re: K211656
Trade/Device Name: 3D Echo v1.1
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ, IYO
Dated: May 27, 2021
Received: May 28, 2021

Dear Mr. Bom:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211656

Device Name
3D Echo v1.1

Indications for Use *(Describe)*
JointVue's 3D Echo v1.1 is a software application for the display and 3D visualization of ultrasound volume data derived from the Terason uSmart3200T ultrasound system. It is designed to allow the user to observe images and perform analyses of musculoskeletal structures using the ultrasound volume data acquired with the Terason ultrasound scanner. Typical users of this system are trained medical professionals including physicians, nurses, and technicians.

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 - K211656

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

I. SUBMITTER

JointVue LLC
2450 E.J. Chapman Drive Suite 104A
Knoxville, TN 37996, USA
+1.410.258.2770

Contact Person: Maja Ward
Date Prepared: June 22, 2021

II. DEVICE

Name of Device:	3D Echo v1.1
Classification Name:	Medical image management and processing system
Regulation:	21 CFR § 892.2050
Regulatory Class:	Class II
Product Classification Code:	Primary: LLZ Secondary: IYO

III. PREDICATE DEVICE

Predicate Manufacturer:	JointVue, LLC
Predicate Trade Name:	3D Echo
Predicate 510(k):	K172513

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

JointVue's 3D Echo is a software application that uses the raw ultrasound signals generated from an imaging ultrasound machine to visualize musculoskeletal structures in three dimensions. The 3D Echo v1.1 includes the following device modifications from 3D Echo v1.0:

1. software is updated for interoperability with Terason 3200T+ Ultrasound system
2. the ultrasound hardware is Terason 3200T+ Ultrasound with Terason 14L3 Linear transducer instead of the SonixOne tablet-based portable ultrasound system
3. the NDI 3D Guidance driveBAY™ tracking unit is replaced by the 3D Guidance trakSTAR™ tracking unit (same system but with an internal power supply))
4. Different GCX system cart designed for Terason 3200T+ Ultrasound
5. Custom transducer/sensor holder now attaches an 800 model EM sensor to the exterior of the ultrasound transducer
6. Designed for use with medically approved probe cover

V. INDICATIONS FOR USE

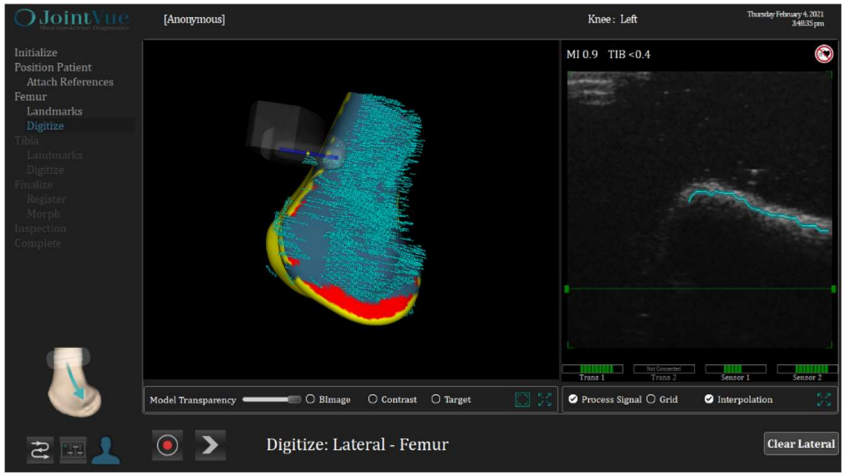
JointVue's 3D Echo v1.1 is a software application for the display and 3D visualization of ultrasound volume data derived from the Terason uSmart3200T ultrasound system. It is designed to allow the user to

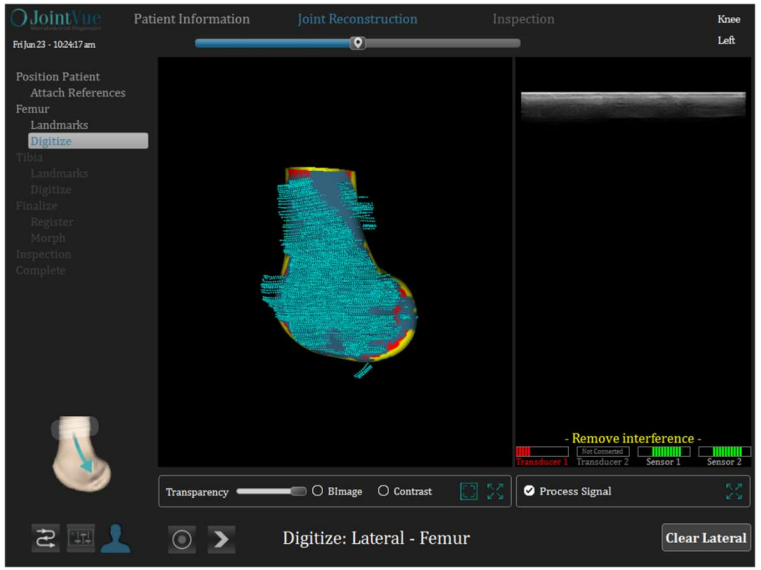
observe images and perform analyses of musculoskeletal structures using the ultrasound volume data acquired with the Terason ultrasound scanner. Typical users of this system are trained medical professionals including physicians, nurses, and technicians.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVCE

Table 1 – Comparison of 3D Echo v1.1 with 3D Echo (K172513)

	3D Echo v1.1 - K211656	3D Echo – K172513	Comparison
Indications for Use	JointVue's 3D Echo v1.1 is a software application for the display and 3D visualization of ultrasound volume data derived from the Terason uSmart3200T ultrasound system. It is designed to allow the user to observe images and perform analyses of musculoskeletal structures using the ultrasound volume data acquired with the Terason ultrasound scanner. Typical users of this system are trained medical professionals including physicians, nurses, and technicians.	JointVue's 3D Echo is a software application for the display and 3D visualization of ultrasound volume data derived from the Sonix Ultrasound Scanner. It is designed to allow the user to observe images and perform analyses of musculoskeletal structures using the ultrasound volume data acquired with the Sonix Ultrasound Scanner. Typical users of this system are trained medical professionals including physicians, nurses, and technicians.	The subject and predicate device have the same intended use and users. The only difference in the intended use statements is the name of off the shelf US system the device is deployed on. This new deployment platform didn't change the intended use or users of the device.
Computer Operating System	Windows 10	Windows 7	OS change based on operating system of the new Terason platform.
3D Visualization	Yes (Surface Visualization)	Yes (Surface Visualization)	Same
View Mode Render	Yes (Display Ultrasound Image with 3D Visualization)	Yes (Display Ultrasound Image with 3D Visualization)	Same
Contouring	Yes	Yes	Same
US Image Visualization	Yes	Yes	Same

User Interface	**3D Echo v1.1**  **Predicate: 3D Echo v1.0 (K172513)**	Functionally identical with small improvements: Displays Patient Information on top banner, Acoustic Indices and active EM field warning in 2D B.

The subject device and predicate device have equivalent indications for use and technological characteristics, with the exception of:

1. Software is updated for interoperability with Terason 3200T+ Ultrasound system.
2. The ultrasound hardware is Terason 3200T+ Ultrasound with Terason 14L3 Linear transducer instead of the SonixOne tablet-based portable ultrasound system.
3. The NDI 3D Guidance driveBAY™ tracking unit is replaced by the 3D Guidance trakSTAR™ tracking unit (same system but with an internal power supply).
4. System cart is designed for the Terason 3200T+ Ultrasound by the same manufacturer as the predicate device (GCX).
5. Custom transducer/sensor holder now attaches an NDI Model 800 EM sensor to the exterior of the ultrasound transducer.
6. Designed for use with medically approved Sheathes probe covers (K153212).

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Sterilization & Shelf-life Testing

Not applicable to this 510(k) notification. The subject device is software and therefore sterilization and shelf-life are not applicable to the subject device. The accessories used with the software are non-sterile and therefore sterilization validation is not applicable to the accessories either. Shelf-life is not applicable to the accessories because of low likelihood of time-dependent product degradation. Therefore, no sterilization validation or aging data is required to demonstrate device safety and effectiveness.

Biocompatibility Testing

The subject device is software and therefore biocompatibility is not applicable (i.e. there are no direct or indirect tissue-contacting components associated with the software itself). All patient contacting components are accessories to the software that have already been cleared by the FDA, and biocompatibility data for those accessories is provided in those submissions.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety testing in accordance with IEC 60601-1 and EMC testing in accordance with IEC 60601-1-2 was performed for the EM Tracking unit. All other electrical safety and EMC testing is found in the FDA submissions for the accessory devices.

Software Verification Testing

Risk analysis and software verification testing was provided to demonstrate safety and efficacy of the subject device in accordance with IEC 62304.

Benchtop Performance Testing

3D Echo v1.1 system performance was validated through a non-clinical benchtop testing performed on physical phantom models simulating knee, including:

-A 3D Echo v1.1 system was utilized to obtain a sample (equivalent in size to that of the predicate validation test) of 3D models of the femur and tibia bone models.

-The surface of these models was compared to the manufacturer provided CAD models to determine the RMS error of the 3D Echo v1.1 generated models.

-Key anatomical landmarks were identified on the surface of both the 3D Echo generated models and provided models which were then used to identify the target axes of the model. These axes were compared between 3D Echo model and provided model to assess the angular error in degrees.

-The surface and angular error in the sample models were statistically analyzed against both the accuracy requirements and performance of the predicate system.

Testing Conclusion
The 3D Echo v1.1 system generated models contained statistically less surface error and measured angular rotation errors than the predicate device. Every model generated by the system met accuracy requirements of the system. Taken with complete verification, software meets all predicate requirements with no additional human factor risks identified in the risk analysis and the 3D Echo v1.1 system has been validated as equivalent in performance and safety as the predicate 3D Echo v1.0 (K172513).

Mechanical and acoustic Testing
Tip testing was performed on the mobile cart provided with the device to demonstrate safety of the mobile cart.

Usability Testing
3D Echo version 1.1 has been modified to operate on the Terason 3200+ Ultrasound platform integrated with the 3D Ascension (now NDI) Guidance System used in the predicate device. No significant changes were made to the user interface or functionality of the software, and no change has been done to the core algorithm for signal detection or morphing. No changes to the product requirements, functionality or risk analysis introduced new usability risks which would require re-validation or repeating of human factor validation from the previous 510(K).

Animal Study
Animal performance testing was not required to demonstrate safety and effectiveness of the device.

Human Clinical Performance Testing
Clinical testing was not required to demonstrate the safety and effectiveness of the device.

VIII. CONCLUSIONS

Both subject and predicate device has the same intended use. There was no change between subject and predicate device in: 1) user interface workflow. 2) core algorithm for signal processing. 3) core algorithm for 3D bone reconstruction. Non-clinical, simulated use testing was conducted to compare the performance of the subject device and the predicate device using identical inputs. Testing results demonstrated that performance of the subject device is equivalent to the predicate device for each of the technical specifications.

A risk analysis was completed, and risk controls were implemented. The ergonomics of patient and user interfaces have not been altered from the predicate version of the device. Performance testing results support claims that the subject device is substantially equivalent to the predicate device with regard to safety and efficacy.