JointVue, LLC
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
BUFFALO MN 55313

Re: K172513
  Trade/Device Name: 3D Echo
  Regulation Number: 21 CFR 892.2050
  Regulation Name: Picture archiving and communications system
  Regulatory Class: II
  Product Code: LLZ
  Dated: August 18, 2017
  Received: August 21, 2017

Dear Mr. Job:

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 (DICE) 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 (DICE) 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,

[Signature]

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure
Indications for Use

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.

Type of Use (Select one or both, as applicable)

- [x] 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.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

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510(k) SUMMARY

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
   2099 Thunderhead Rd., Suite 104
   Knoxville TN, 37922
   Tel: (877) 725-6920 x101

   Contact Person: Mohamed R. Mahfouz,
   Title: President/CEO
   Date Prepared: August 4, 2017

II. DEVICE
   Name of Device: 3D Echo
   Classification Name: Picture Archiving and Communications System
   Regulation: 21 CFR 892.2050
   Regulatory Class: Class II
   Product Classification Code: LLZ

III. PREDICATE DEVICE
   Predicate Manufacturer: Samsung Medison CO., LTD
   Predicate Trade Name: 5D Viewer
   Predicate 510(k): K161955

   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 software is pre-loaded on one of the following two ultrasound systems: 1) SonixOne, a tablet-based system; or 2) SonixTouch Q+ with linear transducer (BK Ultrasound model L14-5/38 GPS) and driveBAY™ tracking unit (Ascension Technology Corporation). There are also two electromagnetic (EM) sensors (Ascension 6DOF sensors, model 800, part #600786) included with the JointVue 3D echo software to identify the relative location of the ultrasound probe. Finally, there is a foot switch (stuete model MKF-2-MED GP25) included as an input device.

   The major software functions of the JointVue 3D Echo system include the following: 1) the ability to display axial, sagittal, coronal and oblique 2D images; 2) the ability to display the 3D surface of musculoskeletal structures; 3) the ability to display axial
images with 3D visualization; and 4) the ability to provide contouring and US image visualization.

The device is intended to be used in a clinical or hospital environment.

JointVue’s 3D Echo ultrasound system utilizes raw ultrasound signals to detect tissue interfaces and visualize joint anatomy in three dimensions. The system provides clinicians with three-dimensional models of the joint anatomy. Figure 5-1 outlines the overall system flowchart for 3D joint visualization.

![Overall system flow chart](image)

**Figure 5-1. Overall system flow chart**

**V. INDICATIONS FOR USE**

JointVue 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 analysis of musculoskeletal structures using the ultrasound volume data acquired with the Sonix Ultrasound Scanner. Typical users of this system are trained professionals, including physicians, nurses, and technicians.

**VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE**

The following characteristics were compared between the subject device and the predicate device in order to demonstrate substantial equivalence:

- **Intended Use / Indications for Use** – The predicate and subject device have equivalent intended use.
- **Materials** – Not applicable, because both are software devices and do not have patient contact.
- **Design Features** – The predicate and subject device design features are summarized in comparison Table 5-1.
- **Energy Source** – Subject device is operated on SonixOne or SonixTouch Q+ that can operate via battery or mains power, while the predicate is loaded on a computer that can operate via battery or mains power.
- **Performance Testing** – The predicate and subject device have equivalent precision and accuracy based upon benchtop testing using a phantom.
Table 5-1

<table>
<thead>
<tr>
<th>Feature</th>
<th>Subject Device (3D Echo)</th>
<th>Predicate Device (5D Viewer)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Computer Operating System</td>
<td>Windows 7</td>
<td>Windows 7</td>
</tr>
<tr>
<td>2D Image Display</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Axial</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Sagittal</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Coronal</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Oblique</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>3D Visualization</td>
<td>Yes (Surface Visualization)</td>
<td>Yes (Volumetric Visualization)</td>
</tr>
<tr>
<td>View Mode Render</td>
<td>Yes (Display Axial Image with 3D visualization)</td>
<td>Yes (Display Axial image with 3D image)</td>
</tr>
<tr>
<td>Contouring</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>US Image Visualization</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

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

Biocompatibility Testing
Not Applicable to the subject device, because the device is software. Accessory that has patient contact is already used for another 510(k) cleared device that has equivalent duration of contact and type of contact.

Electrical safety and electromagnetic compatibility (EMC)
Not applicable to the subject device, because the device is software. Accessory that runs the software is already 510(k) cleared device that has been evaluated for electrical safety and EMC.

Software Verification and Validation Testing
Software verification and validation testing was provided to demonstrate safety and efficacy of the subject device. This includes a hazard analysis, and the potential hazards have been classified as a moderate level of concern (LOC), because the software is an accessory to a Class 2 ultrasound system.

Mechanical and acoustic Testing
Benchtop testing using a phantom was presented to demonstrate safety and effectiveness of the device with the same accuracy and precision as the predicate device.

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

Clinical Studies
Clinical testing was not required to demonstrate the safety and effectiveness of the 3D Echo software.
VIII. CONCLUSIONS
The subject device is equivalent to the predicate device with regard to safety and efficacy. This conclusion is based upon a comparison of intended use, technological characteristics and benchtop testing.