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

Re:  K170167
   Trade/Device Name:  True 3D Viewer Software
   Regulation Number:  21 CFR 892.2050
   Regulation Name:  Picture archiving and communications system
   Regulatory Class:  II
   Product Code:  LLZ
   Dated:  February 22, 2017
   Received:  February 23, 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 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 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 yours,

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

510(k) Number (if known)
K170167

Device Name

True 3D Viewer Software

Indications for Use (Describe)
The True 3D Viewer Software is intended for processing, review, analysis, communication and media interchange of digital images acquired from CT, MRI and Ultrasound sources. It is also intended as software for pre-operative analysis of surgical options. The True 3D Viewer Software is designed for use only with performance tested hardware specified in the user documentation. The device is intended to be used by health care professionals, who are responsible for making all final patient management decisions.

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.

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

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**510(k) Summary**

**Prepared March 1, 2017**

**Sponsor:**
EchoPixel Inc.
2490 Hospital Dr.
Suite 310
Mountain View CA 94040

**Contact Person:**
Sergio Aguirre

**Telephone:**
(650) 404 7097

**Fax:**
(844) 273 7766

**Submission Date:**
December 20, 2016

**Device Name:**
True 3D Viewer Software

**Common Name:**
Imaging Software

**Classification:**

Regulatory Class: II

Review Category: System, image processing, radiological

Classification Panel: Radiology

### A. Legally Marketed Predicate Devices

The modified True 3D Viewer Software is substantially equivalent to the True 3D Viewer cleared pursuant to K142107.

### B. Device Description:

The True 3D Viewer Software is a software application that enables a Health Care Professional (HCP) to visualize and interact with DICOM image data, from CT, MRI and Ultrasound imaging modalities, to assist in clinical decision making.

The application loads DICOM image data and presents a stereoscopic 3D rendered view of the DICOM image data. The True 3D Viewer Software application enables HCPs to visualize and interact with image data and depictions of tissue and organs in an open 3D space as if they were real physical objects. The objects that the software will display are 2D MPR images, 3D volumes, 3D surfaces, labels, and measurements. The system is intended for use in the clinic or hospital settings. Information on performance tested hardware that is provided by the user is described in product labeling.
C. Intended Use

The True 3D Viewer Software is intended for processing, review, analysis, communication and media interchange of digital images acquired from CT, MRI and Ultrasound sources. It is also intended as software for pre-operative analysis of surgical options. The True 3D Viewer Software is designed for use only with performance tested hardware specified in the user documentation. The device is intended to be used by health care professionals, who are responsible for making all final patient management decisions.

D. Substantial Equivalence

<table>
<thead>
<tr>
<th>Predicate Device</th>
<th>Subject Device</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications for Use</strong></td>
<td><strong>Modification</strong></td>
</tr>
<tr>
<td>Intended as a medical diagnostic imaging system that allows the processing, review, analysis, communication and media interchange of multi-dimensional digital images acquired from CT or MR imaging devices. It is also intended as pre-operative software for simulating / evaluating surgical treatment options. The True 3D Viewer is designed for use by health care professionals and is intended to assist the clinician who is responsible for making all final patient management decisions.</td>
<td>The True 3D Viewer Software is intended for processing, review, analysis, communication and media interchange of digital images acquired from CT, MRI and Ultrasound sources. It is also intended as software for pre-operative analysis of surgical options. The True 3D Viewer Software is designed for use only with performance tested hardware specified in the user documentation. The device is intended to be used by health care professionals, who are responsible for making all final patient management decisions.</td>
</tr>
<tr>
<td><strong>Intended Users</strong></td>
<td><strong>Intended Users</strong></td>
</tr>
<tr>
<td>Health Care Professionals</td>
<td>Health Care Professionals</td>
</tr>
<tr>
<td><strong>Class II</strong></td>
<td><strong>Class II</strong></td>
</tr>
<tr>
<td><strong>Regulation / Code</strong></td>
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</tr>
<tr>
<td>21CFR 892.2050; LLZ</td>
<td>21CFR 892.2050; LLZ</td>
</tr>
<tr>
<td><strong>Image analysis features:</strong></td>
<td><strong>Image analysis features:</strong></td>
</tr>
<tr>
<td>Interactive manipulation, tag, annotate, measure, segment</td>
<td>Interactive manipulation, tag, annotate, measure, segment</td>
</tr>
<tr>
<td><strong>Components</strong></td>
<td><strong>Components</strong></td>
</tr>
<tr>
<td>Hardware and software</td>
<td>Software only</td>
</tr>
<tr>
<td><strong>Hardware</strong></td>
<td><strong>Hardware</strong></td>
</tr>
<tr>
<td>Included in system</td>
<td>Provided by user</td>
</tr>
<tr>
<td><strong>Display</strong></td>
<td><strong>Display</strong></td>
</tr>
<tr>
<td>Stereoscopic display part of system; 23.6 inch (Diagonal); Resolution – 1980x1080 full HD; Aspect Ratio – 16:9; Contrast Ratio – 50:1 for 2D and 3D; Color – 16.7 million; Frame Rate – 120 Hz</td>
<td>Stereoscopic display; Performance tested hardware is provided by user</td>
</tr>
</tbody>
</table>
Stylus
Stylus part of system; Buttons – Three programmable buttons; Tracking: 6 degrees of freedom (DOF) sensor; Vibrate Function – Small DC vibrating motor; Infrared LED – 2 IR LED’s, one at each edge
Stylus; Performance tested hardware is provided by user

3D Glasses
3D glasses are part of system; Circular Polarized passive eyewear with trackable markers
3D glasses; Performance tested hardware is provided by user

Personal computer (PC)
PC part of system; Windows 7 or 10 (64bit); Four core 2.5 GHz or equivalent Zeon processor; 8 GB of system memory (RAM); NVidia Quadro Graphics Processing Unit (GPU) with 4GB of video memory; Open-GL 1.4 support (or later) stereo compatible graphics with DVI-d and/or Display Port 500GB drive
PC Performance tested hardware is provided by user

Based on the above comparison there is both reduced capability stated in the indications for use as well as some additional capability and software enhancements. Based on the performance data provided in the submission these differences do not introduce new issues related to safety and efficacy.

**Comparison Table 2 – Technological Characteristics**

<table>
<thead>
<tr>
<th>Feature</th>
<th>Predicate Device EchoPixel True 3D Viewer K142107</th>
<th>Subject Device Echo Pixel Modified True 3D Viewer Software</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Source</td>
<td>CT and MR DICOM Images</td>
<td>CT, MR and Ultrasound DICOM Images</td>
</tr>
<tr>
<td>DICOM compliant</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Display Images</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>3D display mode</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Select Images for closer examination</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Original 2D image remains on the display screen during other views</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Human intervention for interpretation of images</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Multi-dimensional visualization</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Interactively manipulate images in real time to visualize anatomy | Yes | Yes
Visual Tracking | Yes | Yes
Provides the viewer the ability to view spatially registered 2D MPR | Yes | Yes
Interact with images using stylus control | Yes | Yes

In summary based on the comparison of technology technological characteristics of the subject device compared to the predicate are substantially equivalent. Based on the performance data provided in the submission these differences do not introduce new issues related to safety and efficacy.

**E. Performance Data**

Every specification of the True 3D Viewer Software device has been validated according to the company’s documented development and test procedures. The verification and validation testing included testing to the following applicable standard:

- PS 3.1 - 3.20 (2016), Digital Imaging and Communications in Medicine (DICOM) Set PS 3.1
- ISO 14971 –Standard for the Application of Risk Management to Medical Devices
- IEC/TR 80002-1:2009 -Medical device software -- Part 1: Guidance on the application of ISO 14971 to medical device software
- IEC 62304- Medical Device Software-Software Lifecycle Processes

Verification and validation testing were completed in accordance with the company’s Design Control process in compliance with 21 CFR Part 820.30, which included testing fulfilling the requirements of FDA “Guidance on Software Contained in Medical Devices”. Potential risks were analyzed and satisfactorily mitigated in the device design.

**F. Conclusion**

The True 3D Viewer Software is substantially equivalent to the predicate device with regards to intended use and technological characteristics. Results of performance testing demonstrated that the device met the design requirements and as well as the user needs.