DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

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

January 21, 2015

Re: K142107
Trade/Device Name: EchoPixel True 3D Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 30, 2014
Received: January 2, 2015

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,

for

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)* K142107
N/A

Device Name
EchoPixel True 3D Viewer

Indications for Use *(Describe)*
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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Attachment 1

510(k) Summary
December 15, 2014

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

Contact Person: Sergio Aguirre

Telephone: (650) 404 7097

Fax: (650) 941 5795

Submission Date: June 3, 2014

Device Name: EchoPixel True 3D Viewer (t3 Viewer)

Common Name: Imaging Software System

Classification:

Regulatory Class:	II
Review Category:	System, image processing, radiological 21CFR892.2050 (LLZ)
Classification Panel:	Radiology

A. Legally Marketed Predicate Devices

The t3D Viewer is substantially equivalent to the "Primary" predicate, the Surgical Theater Surgery Rehearsal Platform (K123023) with regard to both its intended use and its core technological characteristics. The Vitrea 2 v3.8 manufactured by Vital Images (K052632) is a "reference" predicate and has an intended use and core technology that is also substantially equivalent to the t3D Viewer.

B. Device Description:

The True 3D Viewer system is comprised of a commercial off the shelf hardware platform and a proprietary software application that enables a health care professional (HCP) to visualize and interact with CT and MRI DICOM image data to assist in clinical decision making.

The t3D-Viewer system hardware platform is comprised of an off the shelf stereoscopic display, an optical or electromagnetic motion tracking system and a computer system.
The t3D-Viewer software application loads DICOM image data and presents a stereoscopic 3D rendered view of the DICOM image data. The t3D-Viewer software application enables HCPs to

visualize and interact with image data and depictions of tissue and organs as if they were real physical objects.

C. Intended Use

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 preoperative 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.

D. Substantial Equivalence

Primary Predicate Surgical Theater Surgery Rehearsal Platform K123023	Reference Predicate Vital Images Vitrea 2 K052632	Subject Device True 3D Viewer Echo Pixel
intended for use as a software inter-face and image segmentation system for the transfer of imaging information from CT or MR medical scanner to an output file. It is also intended as pre-operative software for simulating/evaluating surgical treatment options.	Vitrea 2 is a medical diagnostic system that allows the processing, review, analysis, communication and media interchange of multi-dimensional digital images acquired from a variety of imaging devices.	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.
Intended Users Health Care Professionals	Intended Users Health Care Professionals	Intended Users Health Care Professionals
Intended Environment for Use	Healthcare facilities such as hospitals and clinics	Healthcare facilities such as hospitals and clinics
Class II	Class II	Class II
21CFR 892.2050; LLZ	21CFR 892.2050; LLZ	21CFR 892.2050; LLZ
Image analysis features: interactive manipulation, tag, annotate, measure, segment	Image analysis features: interactive manipulation, tag, annotate, measure, segment	Image analysis features: interactive manipulation, tag, annotate, measure, segment

E. Performance Data

- Every specification of the True 3D Viewer device has been validated according to the company's documented development and test procedures. The verification and validation testing conducted by a certified test laboratory included testing to the following

applicable standards: IEC EN, ANSI 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (3rd Edition),

- IEC60601-1-2 Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests:2007-03,
- Risk Management, in accordance with IEC 60601-1 3rd Ed. and ISO 14971 and IEC 60601-1-4 or Clause 14.
- NEMA PS 3.1 - 3.18 (2008), Digital Imaging and Communications in Medicine (DICOM) Set PS 3.1

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 that fulfillsthe requirements of FDA "Guidance on Software Contained in Medical Devices". Potential risks were analyzed and satisfactorily mitigated in the device design. Verification and validation was performed on qualified phantoms as well as in simulated use conditions.

F. Conclusion

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