DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 3, 2017

Ceevra, Inc.
% Mr. Russ Yoshinaka
Chief Executive Officer
3960 Franke Lane
LAFAYETTE CA 94549

Re: K171356
Trade/Device Name: Clarity Reveal
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 10, 2017
Received: July 12, 2017

Dear Mr. Yoshinaka:

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.
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)*
K171356

Device Name
Clarity Reveal

Indications for Use *(Describe)*
Clarity Reveal is intended as a medical 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 software for preoperative surgical planning. Clarity Reveal is designed for use by healthcare 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 5. 510(k) Summary

1. General Information

510(k) Sponsor	Ceevra, Inc.
Address	180 Sansome St., Floor 4 San Francisco, CA 94104
Correspondence Person	Rory A. Carrillo Quality and Regulatory Ceevra, Inc.
Contact Information	Email: rcarrillo@gmail.com Phone: 562-533-7010
Date Prepared	July 14, 2017

2. Proposed Device

Proprietary Name	*Clarity Reveal*
Common Name	*Reveal*
Classification Name	System, Image Processing, Radiological
Regulation Number	21 CFR 892.2050
Regulation Name	Picture archiving and communication system
Product Code	LLZ
Regulatory Class	II

3. Predicate Device

Proprietary Name	*EchoPixel True3D Viewer (t3 Viewer)*
Premarket Notification	K142107
Classification Name	System, Image Processing, Radiological
Regulation Number	21 CFR 892.2050
Regulation Name	Picture archiving and communications system
Product Code	LLZ
Regulatory Class	II

4. Device Description

Clarity Reveal is a software-only device that allows clinicians to review CT and MR image data in three-dimensional (3D) format and/or stereoscopic 3D format (commonly known as virtual reality, or VR). The 3D and VR images are accessible through the Clarity Reveal mobile application which is used by clinicians for preoperative planning.

Clarity Reveal includes two main software-based user interface components, the Processing Interface and Viewer Interface. The Processing Interface is hosted on a cloud-based, virtual workstation and only accessed by authorized personnel, such as an imaging technician. The Processing Interface contains a graphical user interface where an imaging technician can select DICOM-compatible medical images, segment such images, and initiate processing into a 3D

format. The Viewer Interface is a mobile application that is accessible via a compatible, touch-screen enabled, off-the-shelf mobile device to allow for clinicians to review the medical images in 3D and/or VR formats. Only when the compatible mobile device is used in conjunction with a compatible off-the-shelf VR headset can the surgeon view medical images in the VR format.

The product is intended to be used by trained medical professionals, including imaging technicians and clinicians/surgeons, and is used to assist in clinical decision making.

5. Intended Use

Clarity Reveal is intended as a medical 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 software for preoperative surgical planning. Clarity Reveal 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.

6. Substantial Equivalence

Feature/ Function	**Proposed Device:** Clarity Reveal	**Predicate Device:** EchoPixel True3D Viewer (K142107)
Intended Use	Intended as a medical 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 software for preoperative surgical planning. Clarity Reveal 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 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 malting all final patient management decisions.
Intended Users	Healthcare Professionals	Healthcare Professionals
Intended Environment	Healthcare facilities such as hospitals and clinics	Healthcare facilities such as hospitals and clinics

Feature/ Function	**Proposed Device:** Clarity Reveal	**Predicate Device:** EchoPixel True3D Viewer (K142107)
Device Class	Class II	Class II
Image Analysis Features	Interactive manipulation and segment	Interactive manipulation, tag, annotate, measure, segment

7. Performance Data

Safety and performance of Clarity Reveal *has* been evaluated and verified in accordance with software specifications and applicable performance standards through software verification and validation testing. Additionally, the software validation activities were performed in accordance with *IEC 62304:2006/AC: 2008- Medical device software – Software life cycle processes,* in addition to the FDA Guidance documents, *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"* and *"Content of Premarket Submission for Management of Cybersecurity in Medical Devices."*

8. Conclusion

Based on the information submitted in this premarket notification, and based on the indications for use, technological characteristics and performance testing, Clarity Reveal raises no new questions of safety and effectiveness and is substantially equivalent to the predicate device in terms of safety, efficacy, and performance.