Ceevra, Inc.
℅ Rory Carrillo
Quality/Regulatory
RAC Medical LLC
368 San Carlos St.
SAN FRANCISCO, CA 94104

July 10th, 2018

Re: K173274
Trade/Device Name: Ceevra Reveal 2.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: October 9, 2017
Received: October 12, 2017

Dear Rory Carrillo:

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.

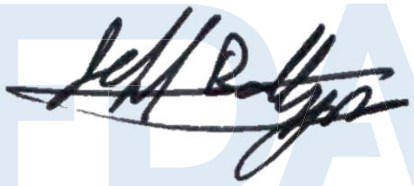
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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
Robert A. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173274

Device Name
Ceevra Reveal 2.0

Indications for Use *(Describe)*
Ceevra Reveal 2.0 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, and as software for the intraoperative display of the aforementioned multi-dimensional digital images. Ceevra Reveal 2.0 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)

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., 2nd Floor 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	June 8, 2018

2. Proposed Device

Proprietary Name	*Ceevra Reveal 2.0*
Common Name	*Reveal 2.0*
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	*Clarity Reveal 1.0*
Premarket Notification	K171356
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

Ceevra Reveal 2.0 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 Ceevra Reveal 2.0 mobile application which is used by clinicians for preoperative surgical planning and for the intraoperative display of the aforementioned 3D and VR images.

Ceevra Reveal 2.0 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.

The 3D images generated using Ceevra Reveal 2.0 are intended to be used in connection with surgical operations in which CT or MR images are used for preoperative planning and/or reviewed intraoperatively.

The manner in which the 3D images are viewed and used does not vary between surgery types. The 3D images are viewed solely from the clinicians' compatible mobile devices, and are not viewed through or otherwise integrated with surgical navigation systems.

5. Intended Use

Ceevra Reveal 2.0 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, and as software for the intraoperative display of the aforementioned multi-dimensional digital images. Ceevra Reveal 2.0 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:** Ceevra Reveal 2.0	**Predicate Device:** Clarity Reveal 1.0 (K171356)
Intended Use	Intended as a medical imaging system that allows the processing, review, analysis, communication	Intended as a medical imaging system that allows the processing, review, analysis, communication and

	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, and as software for the intraoperative display of the aforementioned multi-dimensional digital images. Ceevra Reveal 2.0 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.	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 Users	Health care Professionals	Health care Professionals
Intended Environment	Healthcare facilities such as hospitals and clinics	Healthcare facilities such as hospitals and clinics
Device Class	Class II	Class II
Image Analysis Features	Interactive manipulation and segment	Interactive manipulation and segment
Preoperative Use	Yes	Yes
Intraoperative Use	Yes	No
Pan image	Pan image in any direction	No
PIN Code	Optional 4-digit security code	No

7. Performance Data

Safety and performance of Ceevra Reveal 2.0 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, Ceevra Reveal 2.0 raises no new questions of safety and effectiveness and is substantially equivalent to the predicate device in terms of safety, efficacy, and performance.