Ceevra, Inc.
℅ Ken Koster
CTO
149 New Montgomery Street, 4th Fl.
SAN FRANCISCO CA 94105

April 25, 2023

Re: K222676
Trade/Device Name: Ceevra Reveal 3
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: March 20, 2023
Received: March 21, 2023

Dear Ken Koster:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222676

Device Name
Ceevra Reveal 3

Indications for Use *(Describe)*
Ceevra Reveal 3 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 and that such processing may include the generation of preliminary segmentations of normal anatomy using software that employs machine learning and other computer vision algorithms. 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 3 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.

The machine learning algorithms in use by Ceevra Reveal 3 are for use only for adult patients (22 and over). Three-dimensional images for patients under the age of 22 or of unknown age will be generated without the use of any machine learning algorithms.

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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510(k) Summary

K222676

1. General Information

510(k) Sponsor	Ceevra, Inc.
Address	149 New Montgomery St, 4th Floor San Francisco, CA 94105
Correspondence Person	Ken Koster CTO, Ceevra, Inc.
Contact Information	Email: kkoster@ceevra.com Phone: 415-305-5326
Date Prepared	April 18, 2023

2. Subject Device

Proprietary Name	*Ceevra Reveal 3*
Common Name	*Reveal 3*
Classification Name	Automated Radiological Image Processing Software
Regulation Number	21 CFR 892.2050
Product Code	QIH
Regulatory Class	II

3. Predicate Device

Proprietary Name	*Ceevra Reveal 2.0*
Premarket Notification	K173274
Classification Name	System, Image Processing, Radiological
Regulation Number	21 CFR 892.2050
Product Code	LLZ
Regulatory Class	II

4. Device Description

Ceevra Reveal 3 ("***Reveal 3***"), manufactured by Ceevra, Inc. (the "***Company***"), is a software as a medical device with two main functions: (1) it is used by Company personnel to generate three-dimensional (3D) images from existing patient CT and MR imaging, and (2) it is used by clinicians to view and interact with the 3D images during preoperative planning and intraoperatively.

Clinicians view 3D images via the Reveal 3 Mobile Image Viewer software application which runs on compatible mobile devices, and the Reveal 3 Desktop Image Viewer software application which runs on compatible computers. The 3D images may also be displayed on compatible external displays, or in virtual reality (VR) format with a compatible off-the-shelf VR headset.

Reveal 3 includes additional features that enable clinicians to interact with the 3D images including rotating, zooming, panning, and selectively showing or hiding individual anatomical structures.

5. Indications for Use

Ceevra Reveal 3 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 and that such processing may include the generation of preliminary segmentations of normal anatomy using software that employs machine learning and other computer vision algorithms. 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 3 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.

The machine learning algorithms in use by Ceevra Reveal 3 are for use only for adult patients (22 and over). Three-dimensional images for patients under the age of 22 or of unknown age will be generated without the use of any machine learning algorithms.

6. Substantial Equivalence

As detailed in the following tables, the intended use and technological characteristics of the subject device are substantially equivalent to the predicate devices.

Table 6.1: Comparison of Indications for Use Statements

Subject Device: **Ceevra Reveal 3 (K222676)**	***Primary Predicate:*** **Ceevra Reveal 2.0 (K173274)**
Ceevra Reveal 3 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 and that such processing may include the generation of preliminary segmentations of normal anatomy using software that employs machine	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

learning and other computer vision algorithms. 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 3 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. The machine learning algorithms in use by Ceevra Reveal 3 are for use only for adult patients (22 and over). Three-dimensional images for patients under the age of 22 or of unknown age will be generated without the use of any machine learning algorithms.	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.

Table 7.2: Comparison of Device Characteristics

Feature/ Function	***Subject Device*** **Ceevra Reveal 3 (K222676)**	***Primary Predicate*** **Ceevra Reveal 2.0 (K173274)**
Supported image Modalities	CT and MR	CT and MR
Intended users	Healthcare Professionals	Healthcare 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 3D visualization	Interactive manipulation and 3D visualization
Preoperative viewing of 3D images	Yes	Yes
Intraoperative viewing of 3D images	Yes	Yes
3D images used intraoperatively for real-time guidance, navigation or otherwise integrated with surgical instruments	No	No
Segmentation work performed by	Internal Operators	Internal Operators
Built-in features for end-user to compare CT/MR to device output	No	No
Quantitative outputs calculated by device	No	No
Software generates semi-automated segmentations of abnormal anatomy	No	No
Software generates semi-automated segmentations of certain normal anatomy	Yes	No

7. Performance Data

Safety and performance of Ceevra Reveal 3 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/Amd 1: 2015- 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."*

Four machine learning models are included in Ceevra Reveal 3. These models were verified with datasets of actual CT or MR imaging studies of patients. A total of 141 imaging studies were used to evaluate the device. No dataset contained more than one imaging study from any particular patient. No imaging study used to verify performance was used for training; independence of training and testing data were enforced at the level of the scanning institution, namely, studies sourced from a specific institution were used for either training or testing but could not be used for both. The data used in the device validation ensured diversity in patient population and scanner manufacturers. Subgroup analysis was performed for patient age, patient sex, and scanner manufacturers. For non-prostate related datasets, verification datasets included 40% female patients and 60% male patients. Across all datasets, 32% of patients were under 60 years old, 32% were 60 to 70 years old, 30% were over 70 years old, and 6% were of unknown age. Scanner manufacturers included GE Medical Systems, Siemens, Toshiba, and Philips Medical Systems. Ethnicity of patients in the datasets was reasonably correlated to the overall US population.

Performance was verified by comparing segmentations generated by the machine learning models against segmentations generated by medical professionals from the same imaging study. The performance of the machine learning models, characterized by the Sørensen–Dice coefficient (DSC) or the Hausdorff distance metric at the 95th percentile (HD-95), was as follows: prostate (from MR prostate imaging) 0.87 DSC; bladder (from MR prostate imaging) 0.90 DSC; neurovascular bundles (from MR prostate imaging) 7.8 mm HD-95; kidney (from CT abdomen imaging) 0.89 DSC; kidney (from MR abdomen imaging) 0.87 DSC; artery (from CT abdomen imaging) 0.87 DSC; artery (from MR abdomen imaging) 0.83 DSC; vein (from CT abdomen imaging) 0.86 DSC; vein (from MR abdomen imaging) 0.81 DSC; artery (from CT chest imaging) 0.85 DSC; vein (from CT chest imaging) 0.81 DSC.

8. Conclusion

Ceevra Reveal 3 is deemed to be substantially equivalent to its predicate device based on indications for use, technological characteristics and performance testing. Ceevra Reveal 3 raises no new questions related to safety or effectiveness.