Ceevra, Inc.
Ken Koster
Cto
149 New Montgomery St.
4th Floor
San Francisco, CA 94105

December 5, 2023

Re: K233568
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: November 6, 2023
Received: November 6, 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
Assistant Director
DHT8B: Division of Radiologic 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233568

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.

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

510(k) Summary

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	December 4, 2023

2. Updated 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. Originally Cleared Device

Proprietary Name	*Ceevra Reveal 3*
Common Name	*Reveal 3*
Premarket Notification	K222676
Classification Name	Automated Radiological Image Processing Software
Regulation Number	21 CFR 892.2050
Product Code	QIH
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 features that enable clinicians to interact with the 3D images including rotating,

zooming, panning, selectively showing or hiding individual anatomical structures, and viewing measurements of or between anatomical structures.

5. Intended 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 device.

Table 6.1: Comparison of Intended Use Statements

Updated Device: **Ceevra Reveal 3+**	**Originally Cleared Device:** **Ceevra Reveal 3 (K222676)**
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.	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.

Table 6.2: Comparison of Technological Characteristics

Feature/ Function	Updated Device: Ceevra Reveal 3+	Originally Cleared Device: Ceevra Reveal 3 (K222676)
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 use	Yes	Yes
Intraoperative use	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 measurements calculated by device	Volume of structure, diameter of structure, distance between two points	None
Software generates semi-automated segmentations of abnormal anatomy	No	No
Software generates semi-automated segmentations of certain normal anatomy	Yes	Yes

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."*

Machine Learning Models

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.

Measurement Features

The accuracy of measurement features has been validated on phantom data and on datasets of actual CT or MR imaging studies of patients, including CT and MR imaging studies processed with machine learning models. The types of measurements verified were: volumes of structures, diameters of structures, and distances between two points. All three types of measurements produced by Ceevra Reveal 3+ were verified to be accurate within a mean difference of +/- 10%.

8. Conclusion

Based on the intended use, indications for use, technological characteristics, and performance comparison to the originally cleared Reveal 3 device (K222676), the updated Ceevra Reveal 3+ device is deemed to not raise new questions of safety and effectiveness and is substantially equivalent to the originally cleared device in terms of safety, efficacy, and performance.