August 25, 2026

Ceevra, Inc.
Ken Koster ,CTO
465 California St.
7th Floor
San Francisco, CA 94104

Re: K261595
Trade/Device Name: Ceevra Reveal 4
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: May 13, 2026
Received: May 14, 2026

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an

established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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, 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261595

Please provide the device trade name(s).

Ceevra Reveal 4

Please provide your Indications for Use below.

Ceevra Reveal 4 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, MR, or PET 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 4 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 4 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.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☒ Neonates/Newborns (Birth to < 29 days old) ☒ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

K261595

1. General Information

510(k) Sponsor	Ceevra, Inc.
Address	465 California St., 7th Floor San Francisco CA 94104
Correspondence Person	Ken Koster CTO, Ceevra, Inc.
Contact Information	Email: kkoster@ceevra.com Phone: 415-305-5326
Date Prepared	July 28, 2026

2. Subject Device

Proprietary Name	*Ceevra Reveal 4*
Common Name	*Reveal 4*
Premarket Notification	K261595
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 3+*
Common Name	*Reveal 3+*
Premarket Notification	K243933
Classification Name	Automated Radiological Image Processing Software
Regulation Number	21 CFR 892.2050
Product Code	QIH
Regulatory Class	II

4. Device Description

Ceevra Reveal 4 ("***Reveal 4***"), 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, MR, and PET 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 Mobile Image Viewer software application which runs on compatible mobile devices, and the Desktop Image Viewer software application which runs on compatible computers. The 3D images may also be displayed on compatible external displays.

Reveal 4 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 4 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, MR, or PET 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 4 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 4 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. The only difference in language between the statements is in bold and underlined.

Table 6.1: Comparison of Intended Use Statements

Ceevra Reveal 4	**Predicate Device: Ceevra Reveal 3+ (K243933)**
Ceevra Reveal **4** 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, MR , **or**	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

Ceevra Reveal 4	Predicate Device: Ceevra Reveal 3+ (K243933)
PET 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 **4** 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 **4** 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.	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	Ceevra Reveal 4	Ceevra Reveal 3+ (K243933)
Supported image Modalities	CT, MR, and PET	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

Feature/ Function	Ceevra Reveal 4	Ceevra Reveal 3+ (K243933)
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, SUV of structures from PET imaging	Volume of structure, diameter of structure, distance between two points
Software generates semi-automated segmentations of abnormal anatomy	No	No
Software generates semi-automated segmentations of certain normal anatomy	Yes	Yes
Software can combine two input 3D images into one merged 3D image	Yes	No
Anatomical areas and image modalities for which machine learning models generate semi-automated segmentations normal anatomy	Kidney-related (CT and MR) Lung-related (CT) Prostate-related (MR) Uterus-related (MR) Abdominopelvic bone (CT)	Kidney-related (CT and MR) Lung-related (CT) Prostate-related (MR)

7. Performance Data

Safety and performance of Ceevra Reveal 4 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 *"Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions."*

Six machine learning models are included in Reveal 4. These models were verified with datasets of actual CT or MR imaging studies of patients. A total of 201 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 41% female patients and 59% male patients. Across all datasets, 44% of patients were under 60 years old, 25% were 60 to 70 years old, 27% were over 70 years old, and 4% were of unknown age. Scanner manufacturers included GE

Medical Systems, Siemens, Toshiba, Hitachi, 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) 0.90 DSC; bladder (from MR prostate imaging) 0.93 DSC; neurovascular bundles (from MR prostate imaging) 6.6 mm HD-95; kidney (from CT abdomen imaging) 0.92 DSC; kidney (from MR abdomen imaging) 0.89 DSC; artery (from CT abdomen imaging) 0.90 DSC; artery (from MR abdomen imaging) 0.87 DSC; vein (from CT abdomen imaging) 0.88 DSC; vein (from MR abdomen imaging) 0.82 DSC; pulmonary artery (from CT chest imaging) 0.82 DSC; pulmonary vein (from CT chest imaging) 0.83 DSC, airways (from CT chest imaging) 0.82 DSC; bronchopulmonary segments (from CT chest imaging) 0.86 DSC; uterus (from female pelvic MR imaging) 0.90 DSC; bone (from CT abdominopelvic imaging) 0.93 DSC.

The accuracy of measurement features has been validated on phantom data and on datasets of actual CT, MR, or PET imaging studies of patients, including CT and MR imaging studies processed with machine learning models.

The accuracy of Standardized Uptake Value (SUV) measurements derived from PET imaging by Reveal 4 was verified using a validated phantom dataset and validation toolkit, which consists of synthetic DICOM studies with known voxel values (including known SUVmax and SUVmean values for specified regions of interest) and associated acceptance ranges for validation testing. The SUVmax and SUVmean values derived from PET imaging by Reveal 4 were validated against these acceptance ranges. For the regions of interest used for validation testing, the acceptance ranges varied between +/- 1.2% to +/- 5.6% for SUVMax and +/- 1.3% to +/- 10.7% for SUVMean.

8. Predetermined Change Control Plan (PCCP)

The Predetermined Change Control Plan (PCCP) for Reveal 4 specifies modifications the Company may make to iteratively improve the cleared device, together with the methodology used to develop, validate, and implement those modifications. The PCCP authorizes two types of modifications without a new premarket submission: (1) updates to the machine learning models that are part of Reveal 4, where the only changes are re-training on new data or bounded changes to data pre-processing or post-processing; and (2) introduction of machine learning model-based semi-automated segmentations for specified normal anatomical structures not auto-segmented by machine learning models in the cleared version of the device. Before any modification is released, the same performance evaluation methodology used to verify the machine learning models in the cleared device is used to evaluate the modifications: performance is characterized by comparing segmentations generated by the machine learning models against segmentations generated by medical professionals from the same imaging study. The acceptance criteria applied to each modification are specified in the PCCP. Users are informed of device modifications through the Reveal 4 labeling, which is provided in electronic format, is accessed directly from the end-user device,

is updated to reflect each modification implemented under the PCCP, and always displays the most up-to-date information about the machine learning models.

9. Conclusion

Based on the intended use, indications for use, technological characteristics, and performance comparison to the predicate device, the subject device is substantially equivalent to the predicate device.