October 31, 2022

Merit CRO, Inc.
% Maureen O'Connell
President
O'Connell Regulatory Consultants, Inc.
44 Oak Street
Stoneham, Massachusetts 02180

Re: K220929
Trade/Device Name: Excelsior
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: NFJ, LLZ
Dated: September 23, 2022
Received: September 23, 2022

Dear Maureen O'Connell:

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,

Elvin Ng
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
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)*
K220929

Device Name
EXCELSIOR

Indications for Use *(Describe)*

Ophthalmology

The EXCELSIOR Software is intended for use in importing, processing, measurement, and analysis of ophthalmic clinical images as well as in management of clinical data, through a computerized network for use in analysis of images and data obtained in clinical trials.

Radiology

Excelsior is a software solution intended to be used for viewing, manipulation, communication, annotation, analysis, and comparison of medical images from multiple imaging modalities and/or multiple time points. The application supports images, functional data such as PET as well as anatomical datasets, such as CT or MR. Excelsior is a software only medical device to be deployed through a cloud-based computerized network via web applications and customized user interfaces for use in the analysis of images and data obtained in clinical trials. Excelsior enables visualization of information that would otherwise have to be visually compared disjointedly. Excelsior provides analytical and workflow automation tools to help the user assess and document the extent of a disease and/or the response to therapy in accordance with user selected standards and assess changes in imaging findings over multiple time-points. Excelsior supports the interpretation and evaluation of examinations and follow-up documentation of findings for radiologic oncology imaging and data obtained in clinical trials.

The product is intended to be used as a workflow automation tool by trained medical professionals. It is intended to provide image and related information that is interpreted by a trained professional but does not directly generate any diagnosis or potential findings.

Note: The medical professional retains the ultimate responsibility for making the pertinent observations based on their standard practices and established practices related to clinical trial outcomes. Excelsior is a complement to these standard procedures. Excelsior is not to be used in mammography.

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

Merit CRO, Inc.
EXCELSIOR
K220929

510(k) Owner
Merit CRO, Inc.
6527 Normandy Lane
Suite 100
Madison, WI 53719

Submission Correspondent
Maureen O'Connell
O'Connell Regulatory Consultants, Inc.
44 Oak Street
Stoneham, MA 02180
Phone: 978-207-1245

Date Prepared: September 20, 2022

Trade Name of Device
EXCELSIOR

Common or Usual Name
Image Processing Software

Classification Name
Image Processing Software, Ophthalmology, 21 C.F.R. §892.2050
Image Processing Software, Radiology, 21 C.F.R. §892.2050
Class II
Product Codes: NFJ and LLZ

Predicate Devices
Primary:
Merit CRO, Inc. (formerly Eyekor) EXCELSIOR software cleared in K130453

Secondary:
Mint Lesion cleared in K142647

Device Description
The EXCELSIOR software is a cloud-based software that provides a central reading platform integrating remote data collection, quantitative analysis and measurement, storage, and management of ophthalmic and radiological data from DICOM images for clinical trials. The software does not use artificial intelligence or machine learning algorithms.

Indications for Use

Ophthalmology

The EXCELSIOR software is intended for use in importing, processing, measurement, and analysis of ophthalmic clinical images as well as in management of clinical data, through a computerized network for use in analysis of images and data obtained in clinical trials.

Radiology

EXCELSIOR is a software solution intended to be used for viewing, manipulation, communication, annotation, analysis, and comparison of medical images from multiple imaging modalities and/or multiple time points. The application supports images, functional data such as PET as well as anatomical datasets, such as CT or MR. EXCELSIOR is a software only medical device to be deployed through a cloud-based computerized network via web applications and customized user interfaces for use in the analysis of images and data obtained in clinical trials. EXCELSIOR enables visualization of information that would otherwise have to be visually compared disjointedly. EXCELSIOR provides analytical and workflow automation tools to help the user assess and document the extent of a disease and/or the response to therapy in accordance with user selected standards and assess changes in imaging findings over multiple time-points. EXCELSIOR supports the interpretation and evaluation of examinations and follow-up documentation of findings for radiologic oncology imaging and data obtained in clinical trials.

The product is intended to be used as a workflow automation tool by trained medical professionals. It is intended to provide image and related information that is interpreted by a trained professional but does not directly generate any diagnosis or potential findings.

Note: The medical professional retains the ultimate responsibility for making the pertinent observations based on their standard practices and established procedures related to clinical trial outcomes. EXCELSIOR is a complement to these standard procedures. EXCELSIOR is not to be used in mammography.

Substantial Equivalence

Merit CRO, Inc. believes that the EXCELSIOR software described in this notification and for use under the conditions of the proposed labeling is substantially equivalent to legally marketed predicate devices that are Class II medical devices. For Ophthalmic indications for use the primary predicate device is the Merit CRO (formerly Eyekor) EXCELSIOR software cleared in K130453. For radiology indications for use, EXCELSIOR is substantially equivalent to the mint Lesion software cleared in K142647, which is the secondary predicate device.

Regarding Ophthalmology features, both the new version of EXCELSIOR and the version cleared in K130453 are ophthalmic management software devices for use in clinical trials. Additionally, the indications for use are identical. The new EXCELSIOR software is a modification of the cleared EXCELSIOR software. The majority of technological characteristics are identical, however, the new version of EXCELSIOR includes additional image overlay tools, and a video storage and playback capability has been added to the software. These tools and features do not change the intended use of the product and performance data shows that each of these features performs as intended.

The additional tools and features do not raise different questions of safety and effectiveness but represent minor modifications to the software features. The methodology used to validate and verify that the software performs as intended was used to confirm performance of the additional tools and features. The performance data provided supports substantial equivalence with the EXCELSIOR predicate device.

Regarding the Radiology features, the both the new version of EXCELSIOR and the mint Lesion software cleared in K142647 are image management software devices for use in radiology. EXCELSIOR has similar technological characteristics relating to radiology image management. Minor differences with the technological characteristics of the two devices do not change the intended use of the product and performance data is provided which shows that each of these features performs as intended. The additional tools and features do not raise different questions of safety and effectiveness compared to the predicate device. These represent minor modifications to the software features. The methodology used to validate and verify that the software performs as intended was used to confirm performance of the additional tools and features. The performance data provided supports substantial equivalence with the EXCELSIOR predicate device by demonstrating that the software performs as intended.

Performance Data

Software validation and verification testing was performed which showed that the software performs as intended supporting substantial equivalence. Additionally, EXCELSIOR conforms with the DICOM standards which supports substantial equivalence as the primary predicate device conformed with the DICOM standard.