Realize Medical Inc.
℅ Dan La Russa
Co-founder & Chief Product Officer (CPO)
405-2197 Riverside Drive
Ottawa, Ontario K1H 7X3
CANADA

Re: K220649 January 17, 2023
Trade/Device Name: Elucis
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: December 20, 2022
Received: December 20, 2022

Dear Dan La Russa:

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 S. Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging
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)*
K220649

Device Name
Elucis

Indications for Use *(Describe)*

Elucis is intended for use as a software interface and image segmentation system for the transfer of medical imaging information to an output file. It is also intended for measuring and treatment planning.

Elucis should be used in conjunction with expert clinical judgement.

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.

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SECTION 5. 510(k) Summary

405-2197 Riverside Drive
Ottawa, Ontario, Canada
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K220649

Summary Preparation date: 4/18/2022

Device Information	
Item	**Information**
Type of 510(k) submission	Traditional
Sponsor / Submitter:	Name: Dan La Russa Company: Realize Medical Inc. Address: 405-2197 Riverside Drive, Ottawa, ON, Canada, K1H 7X3
Correspondent Contact Information:	Name: Dan La Russa Title: Co-founder and Chief Product Officer (CPO) Phone: 613-883-3461 Email: dan@realizemed.com
Device Common Name:	Image processing system
Device Proprietary Name:	Elucis
Proposed Device Classification Regulation	21 CFR 892.2050
Device Classification Name	System, Image Processing, Radiological
Device Classification	Class II
Classification Product Code	LLZ
Device Review Panel	Radiology
Prior FDA Document Numbers	None
Basis of submission	New Device
Convenience Kit Description	None
Number of Devices in Summary	One

Predicate Device Information	
Predicate Device	Mimics Medical
Predicate Device Manufacturer	Materialise N.V.
Predicate Device Common Name	Image processing system
Predicate Device Premarket Notification 510(k) number	K183105
Predicate Device Classification	Class II
Predicate Device Classification Product Code	LLZ

Device Description

Elucis is a software system for creating, visualizing, and interacting with three-dimensional (3D) models in a desktop 2D environment and an extended (virtual) reality (XR) environment. Medical images (e.g., CT and MRI) and, optionally, 3D structure files in a variety of file formats are used as input. Users can create 3D anatomical models directly from one or more medical images using a variety of manual and semi-automatic image segmentation tools available in the XR environment. These models, and the images from which they were created, can be used to conduct measurements and plan treatments.

The core functionality in Elucis includes the ability to:

- View medical images in a variety of planar and volumetric reformations
- Import medical images in DICOM and other formats and import 3D model files
- Create 3D models from medical images using a variety of common modeling tools
- Review and edit existing 3D models
- Perform measurements on images and models
- Plan treatments using 3D models and associated medical images
- Save and export images, measurements, 3D models, and other treatment planning information

Device Intended Use

Elucis is intended for use as a software interface and image segmentation system for the transfer of medical imaging information to an output file. It is also intended for measuring and treatment planning.

Elucis should be used in conjunction with expert clinical judgement.

Comparison to Predicate Device

Elucis shares the following technological characteristics with the predicate device. This includes the ability to:

- Import 3D model files and medical images in DICOM and other formats,
- View medical images and models in a variety of planar and volumetric reformations,

- Create 3D models from medical images using a variety of common modeling tools
- Perform measurements on images and models
- Plan treatments using 3D models and associated medical images
- Save and export information, including 3D models, images, measurements, and other treatment planning information

The following technological differences exist between the subject and predicate devices:

- Modeling, measurement, and treatment planning activities are performed in a virtual XR environment in the subject device
- Advanced modeling algorithms enable 3D modeling operations, as well as dynamic segmentation of multi-phase (4D) images in real time in the subject device
- Support for collaboration between multiple remote users, both on the desktop and in the accompanying extended (virtual) reality (XR) environment in the subject device
- In support of treatment planning activities, the subject device enables:
    - Models to be moved and/or resized independently
    - Annotations, including mark-ups, voice memos, and other staging elements
- The subject device does not support automated workflows with scripting, nor can it be interfaced with third-party applications for finite element analysis

Despite these technological differences, the additional modeling and annotation capabilities available in the subject device are a matter of convenience for users, and do not affect the format of the final output produced by the system, nor the safety and efficacy of the device.

Performance Data

The overall safety, efficacy, and performance of Elucis was established using software verification and validation tests conducted in accordance with FDA's Guidance for Industry and FDA Staff, entitled "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". Software verification tests were defined and conducted for all specified software requirements. Additional validation tests were conducted to verify geometric accuracy of 3D models and accuracy of measurements. End-user validation was conducted with a group of intended users, representing a diverse mix of clinical roles, educational backgrounds, and experience, to confirm overall usability.

The geometric accuracy of virtual models created in the subject device was assessed via comparisons against the same models made with the predicate device. Results were obtained for a range of anatomical structures and medical image scan types. All observed deviations were within acceptance criteria, demonstrating that Elucis is substantially equivalent to the predicate device for model creation and measurement.

All performance testing results serve to demonstrate the subject device as substantially equivalent to the predicate device.

Summary

Based on a comparison of intended use, technological characteristics, and the outcome of verification and validation tests, Elucis may be deemed substantially equivalent to the Mimics Medical predicate device from

Materialise (K183105). While differences in intended use and technological characteristics exist, they do not alter the intended use of the subject device, its performance characteristics, or safety and risk profile relative to that of the predicate.