Aibolit Technologies, LLC
% Howard Schrayer
Regulatory Consultant
Howard Schrayer
8 Lookout
HILTON HEAD ISLAND SC 29928

Re: K222458
Trade/Device Name: Aibolit 3D+
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH, LLZ,
Dated: December 5, 2022
Received: December 5, 2022

January 12, 2023

Dear Howard Schrayer:

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
DHT 8B: Division of Radiological Imaging Devices and Electronic Products
OHT 8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

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)*
K222458

Device Name
AIBOLIT 3D+

Indications for Use *(Describe)*
Aibolit 3D+ 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 and MRI imaging devices. Aibolit 3D+ is intended as software for preoperative surgical planning, training, patient information and as software for the intraoperative display of the multidimensional digital images. Aibolit 3D+ 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.

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)

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510(k) Summary
(Per 21 CFR 807.92)

Contact: Howard Schrayer
AIbolit Technologies, LLC
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Delray Beach, FL 33446

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Date Prepared: January 11, 2023

Device Trade Name: AIBOLIT 3D+

Manufacturer: AIbolit Technologies, LLC
9616 Moritz Way
Delray Beach, FL 33446

Common Name: Automated Radiological Image Processing Software
Medical image management and processing system

Classification: Class II

Product Code: QIH - LLZ

Regulation: 21 CFR 892.2050

Predicate Devices:

Primary Predicate

Aibolit Technologies, LLC 3D+ System
[510(k) K211443].

Reference Predicate

Ceevra, Inc.
Ceevra Reveal 2.0
Image Processing System
[510(k) K173274]

Indications for Use:

Aibolit 3D+ 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 and MR imaging devices. Aibolit 3D+ is intended as software for preoperative surgical planning, training, patient information and as software for the intraoperative display of the multidimensional digital images. Aibolit 3D+ 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.

Device Description:

Aibolit 3D+ is a web-based stand-alone application that can be presented on a computer connected to the internet. Once the enhanced images are created, they can be used by the physician for case review, patient education, professional training and intraoperative reference.

Aibolit 3D+ is a software only device, which processes CT and MR images from a patient to create 3-dimensional images that may be manipulated to view the anatomy from virtually any perspective. The software also allows for transparent viewing of anatomical structures artifacts inside organs such as ducts, vessels, lesions and entrapped calcifications (stones). Anatomical structures are identified by name and differential coloration to highlight them within the region of interest.

The software may help to facilitate the surgeon's decision-making during planning, review and conduct of surgical procedures and, hence, may potentially help them to decrease or prevent possible errors caused by the misidentification of anatomical structures and their positional relationship.

Substantial Equivalence and Predicate Devices:

The reason for this submission was to add the processing of images derived from MRI DICOM files to the functioning of the primary Aibolit predicate. This functionality is present in the referenced Ceevra predicate. The device was shown to be substantially equivalent to itself [510(k) K211443] and a previously cleared video image processing system, the Ceevra Reveal 2.0 Image Processing System [510(k) K173274].

Predicate Comparison Table

Manufacturer	Albolit Technologies, LLC	Ceevra
Trade Name	AIBOLIT 3D+ Image Processing System	Ceevra Reveal 2.0 Image Processing System
510(k) Number	Subject Device - TBD	K173274
Type of Device/ Product Code /	Radiological Image Processing System / QIH - LLZ	Radiological Image Processing System / LLZ
Regulation / Class	21 CFR 892.2050 – Class II	21 CFR 892.2050 – Class II
Indications for Use	Aibolit 3D+ 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, training, patient information and as software for the intraoperative display of the multidimensional digital images. Aibolit 3D+ 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.	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 multidimensional 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.
Mechanism of Action	Capture and enhancement of (DICOM) digital video images via software-based conversion to 2-D and 3-D anatomical structure images that can be manipulated for viewing	Capture and enhancement of (DICOM) digital video images via software-based conversion to 2-D and 3-D anatomical structure images that can be manipulated for viewing
Intended Users	Health care professionals	Health care professionals
Intended Use Environment	Healthcare facilities such as hospitals and clinics	Healthcare facilities such as hospitals and clinics
Format of Captured Images	DICOM	DICOM

Intended Use	AIBOLIT 3D+ is intended for use 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 multi-dimensional digital images. AIBOLIT 3D+ is designed for use by health care professionals and is intended to assist the clinician who is responsible for making patient management decisions.	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 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.
Security	Data coded and HIPAA compliant	Data coded and HIPAA compliant
Form of Device	AIBOLIT 3D+ is a software only device that permits electronic image uploads, provides image conversion and allows viewing on a mobile device or standard computer monitor.	The Ceevra Reveal 2.0 Video Processor is a software only device that permits electronic image uploads, provides image conversion and allows viewing on a mobile device or standard computer monitor.
Image processing	High-definition digital images	High-definition digital images
Functions	Generation of 2D and 3D images from DICOM data Organ segmentation and structure identification Dimensional and volume references Multi-axis image rotation Organ transparency	Generation of 2D and 3D images from DICOM data Organ segmentation and structure identification Dimensional and volume references Multi-axis image rotation Organ transparency
Body contact	None	None
User Interface and System Work-Flow	Physician uploads DICOM images and specifies desired anatomical segments of interest Radiologist annotates sample (segments) images	Physician uploads DICOM images and specifies desired anatomical segments of interest Imaging technician annotates sample (segments) images

	Radiologist may use add-on software to facilitate annotation of DICOM images under guidance and full control of the Radiologist Radiologist generates multi-axis rotatable image and returns output file to requesting physician	Imaging technician generates multi-axis rotatable image and returns output file to requesting physician
External / Internet Connections	Web-based software	Web-based software
CT / MRI Image Uploading	By requesting physician	By requesting physician
Other User Inputs	List of organ structures to be annotated and displayed, patient ID and demographics	List of organ structures to be annotated and displayed, patient ID and demographics
Image Segmentation	By Radiologist (MD) – Manual annotation is done for all CT and MRI slices with optional use of software as determined by Radiologist and with Radiologist's approval and control	By Imaging Technician – Manual annotation done for all CT and MRI slices – No software used for annotation
Organ identification	By Radiologist	Unknown proprietary method used to identify organ structures
3D Image generation	3D image file generated by 3rd party software (3D Slicer) following Radiologist review and approval of annotation	3D image file generated by 3rd party software
Organ structure identification	Proprietary software assigns color coding to each structure identified by Radiologist and displays color-coded image with labeled key to color/structure identity	Proprietary software assigns color coding to each structure identified by imaging technician and displays color-coded image with key to color/structure identity

Image editing permission	Only the radiologist can edit images following review – User physicians cannot edit images - Physicians have option to show or hide organs on display	Imaging technician can edit images generated by the system software – User physicians cannot edit images - Physicians have option to show or hide organs on display
Device Output Devices	3D image can be displayed on standard monitor or another appropriate display	3D image can be displayed on standard monitor, smart phone (with separate software) or Virtual Imaging 3D headset
Supplemental outputs	Organ structure dimensions, volume, organ labels, patient ID, image date and demographics	Organ structure dimensions, volume, organ labels, patient ID and demographics
Output image manipulation by user	Physician user can show or hide individual organ structures, zoom capability, rotational capability and transparency capability	Physician user can show or hide individual organ structures, zoom capability, rotational capability, transparency capability (current version)

Performance Testing:

Non-clinical performance data was included in the 510(k) submission to demonstrate that the Aibolit software has been validated for its intended use and to support substantial equivalence to the predicate device.

Software verification and validation were performed, and documentation was included in this submission in accordance with FDA Guidance “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”. This includes verification against defined requirements, and validation against user needs. In addition, performance testing included 1) segmentation validation of the Customize software, 2) Repeatability and Reproducibility (R&R) study on the segmentation of multiple internal organ/structure anatomies and 3) accuracy study on 3D model generation for multiple organ structures.

For image segmentation, the device includes optional artificial intelligence including machine learning followed by review by a radiologist. The AI-based algorithm is based on a system that has been trained to identify organs/structures using a dataset of 108 anatomical structures as obtained from medical images (MRI scans) and their corresponding segmentation. The images were evaluated from 3 perspectives by 4 radiologists. After a radiologist establishes contours, the system produces additional segmentations for review by the radiologist.

The following documentation was previously submitted.

Hardware Requirements
Level of Concern Statement
Software Description
Architecture Design
User Manual and Instructions for Use
Software Design Specification
Risk Analysis
Traceability Analysis
Software Validation Report
Usability Evaluation
Software Development Lifecycle
Unresolved Anomalies
Cybersecurity

Additional Testing

Expansion of Software Validation to include MRI validation using multiple organ structures, multiple radiologists and multiple view perspectives. The validation was conducted in accordance with a written protocol with pre-determined acceptance criteria. The validation demonstrated conservation of shape dimensions, volume of the structures in a side-by-side testing comparison with a “ground truth” accepted standard independent of radiologist, organ structure and view perspective.

Conclusion

AIBOLIT 3D+ is substantially equivalent to the previously cleared Aibolit 3D+ system (K211443) and to the Ceevra Reveal 2.0 Image Processing System (K173274) with respect to intended use, principle of operation, general technological characteristics and performance.