January 17, 2024

Clear Guide Medical
℅ Alican Demir
Principal Engineer / Director of Quality Systems
3600 Clipper Mill Road, Suite 400
BALTIMORE, MD 21211

Re: K234030
Trade/Device Name: Clear Guide SCENERGY
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK, IYO, LLZ, ITX
Dated: November 12, 2023
Received: December 20, 2023

Dear Alican Demir:

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K234030

Device Name
Clear Guide SCENERGY

Indications for Use *(Describe)*
The Clear Guide SCENERGY is software that provides fusion of images from Computed Tomography (CT), Magnetic Resonance (MR), and Ultrasound (US) modalities. US images can be fused with either CT or MR.

The Clear Guide SCENERGY utilizes the Clear Guide CORE and Clear Guide Optical Head platform to display images of the target regions and the projected path of the interventional instrument, while taking into account patient movement and deformation. Instrumentation used with the Clear Guide SCENERGY might include an interventional needle or needle-like rigid device, such as a biopsy needle, an aspiration needle, or an ablation needle. The device is intended to be used in any interventional or diagnostic procedure where the combination of these modalities is used for visualization, except for procedures on the brain. The device is intended for use in a clinical setting, in patients of sufficient size (at least 25 kg).

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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510(k) Summary

(per 21 CFR § 807.92)

Submitter's Information

Name	Clear Guide Medical, Inc.
Address	3600 Clipper Mill Road, Suite 400 Baltimore, MD 21211 USA
Phone Number	+1 (443) 602-8950
Contact Person	Alican Demir, PhD Principal Engineer / Director of Quality Systems
Date Prepared	January 15, 2024

Device Information

Trade Name	Clear Guide SCENERGY
Common Name	System, Imaging Software
Classification(s)	JAK Computed tomography x-ray system Class II under 21 CFR 892.1750
	Subsequent/Secondary Classification(s) are:
	IYO Ultrasonic pulsed echo imaging system Class II under 21 CFR 892.1560
	LLZ Medical image management and processing system Class II under 21 CFR 892.2050
	ITX Diagnostic ultrasound transducer Class II under 21 CFR 892.1570

Predicate Device Information

Device Name	Clear Guide SCENERGY (Clear Guide Medical, Inc.)
510(k) Number	K201188
Common Name	System, Imaging Software
Classification(s)	JAK Computed tomography x-ray system Class II under 21 CFR 892.1750
	Subsequent/Secondary Classification(s) for all predicate devices are:
	IYO Ultrasonic pulsed echo imaging system Class II under 21 CFR 892.1560
	LLZ Medical image management and processing system Class II under 21 CFR 892.2050

Device Description

The **CLEAR GUIDE** SCENERGY is a medical guidance and navigation software system that provides image fusion, instrument tracking, marker tracking, and target planning functionalities to operators during image-guided diagnostic or interventional procedures. The system uses data from multiple compatible imaging modalities that includes computed-tomography (CT), magnetic resonance imaging (MRI), or diagnostic ultrasound (US).

The **CLEAR GUIDE** SCENERGY uses optical detection technology to identify and track objects in the field of view. By pairing this information with the aforementioned imaging data, the **CLEAR GUIDE** SCENERGY executes proprietary software algorithms to display fused images in real-time to the clinician. These segmentation and registration algorithms are automated. Segmentation results are deterministic, meaning that new inputs (e.g., a new CT or MRI) would be required to change the segmentation output. Registration can be reset by the user at any time during use.

Intended Use

The device is a stereotaxic accessory intended to provide fusion of images from certain imaging modalities. The device is intended to be used in any interventional or diagnostic procedure where the combination of these modalities is used for visualization, except for procedures on the brain. The device is intended for use in a clinical setting.

Indications For Use

The Clear Guide SCENERGY is software that provides fusion of images from Computed Tomography (CT), Magnetic Resonance (MR), and Ultrasound (US) modalities. US images can be fused with either CT or MR.

The Clear Guide SCENERGY utilizes the Clear Guide CORE and Clear Guide Optical Head platform to display images of the target regions and the projected path of the interventional instrument, while taking into account patient movement and deformation. Instrumentation used with the Clear Guide SCENERGY might include an interventional needle or needle-like rigid device, such as a biopsy needle, an aspiration needle, or an ablation needle. The device is intended to be used in any interventional or diagnostic procedure where the combination of these modalities is used for visualization, except for procedures on the brain. The device is intended for use in a clinical setting, in patients of sufficient size (at least 25 kg).

Technological Characteristics

Real-time marker tracking and instrument guidance is achieved by optical detection of needles or needle-like rigid instrumentation by means of stereo cameras, and overlay of graphical indicators on the input imaging modality (Ultrasound, CT, or MR). Optionally, fiducial markers are attached to the patient and/or instrument to facilitate tracking.

Image fusion is the joining of static, volumetric, high-resolution imaging data (e.g., CT or MRI scans) with real-time, streamed image data (e.g., ultrasound). **CLEAR GUIDE** SCENERGY uses proprietary algorithms capable of combining three input sources (image stream from an ultrasound machine, a static CT/MRI volume, and video feed from the **CLEAR GUIDE** Optical Head) to provide an accurate visual feedback for the underlying image-guided procedure. Fusion of static imaging data (CT/MRI) is facilitated by the application of multi-modality fiducial markers prior the imaging. When Ultrasound and CT/MR fusion is enabled, the real-time ultrasound image stream is shown on the display together with dynamically computed CT/MR slices from the volumetric data, and guidance overlays.

A comparison of **CLEAR GUIDE** SCENERGY's technological characteristics to its predicate device is provided below.

Category	**Modified Device:** Clear Guide SCENERGY	**Predicate Device:** Clear Guide SCENERGY
510(k) Number	K234030	K201188
Product Code	JAK	JAK
Classification Regulation	21 CFR 892.1750	21 CFR 892.1750
Regulatory Class	Class II	Class II
Classification Name	Computed tomography x-ray system	Computed tomography x-ray system
Subsequent Product Code(s)	IYO, LLZ, ITX	IYO, LLZ
Intended Use(s) **(i.e., List of Main Functions)**	- Image Fusion - Instrument Tracking and Guidance	- Image Fusion - Instrument Tracking and Guidance
Indications for Use	The Clear Guide SCENERGY is software that provides fusion of images from Computed Tomography (CT), Magnetic Resonance (MR), and Ultrasound (US) modalities. US images can be fused with either CT or MR. The Clear Guide SCENERGY utilizes the Clear Guide CORE and Clear Guide Optical Head platform to display images of the target regions and the projected path of the interventional instrument, while taking into account patient movement and deformation. Instrumentation used with the Clear Guide SCENERGY might include an interventional needle or needle-like rigid device, such as a biopsy needle, an aspiration needle, or an ablation needle. The device is intended to be used in any interventional or diagnostic procedure where the combination of these modalities is used for visualization, except for procedures on the brain. The device is intended for use in a clinical setting, in patients of sufficient size (at least 25 kg).	The Clear Guide SCENERGY is software that provides fusion of images from Computed Tomography (CT), Magnetic Resonance (MR), and Ultrasound (US) modalities. US images can be fused with either CT or MR. The Clear Guide SCENERGY utilizes the Clear Guide CORE and Clear Guide SuperPROBE platform to display images of the target regions and the projected path of the interventional instrument, while taking into account patient movement and deformation. Instrumentation used with the Clear Guide SCENERGY might include an interventional needle or needle-like rigid device, such as a biopsy needle, an aspiration needle, or an ablation needle. The device is intended to be used in any interventional or diagnostic procedure where the combination of these modalities is used for visualization, except for procedures on the brain. The device is intended for use in a clinical setting, in patients of sufficient size (at least 25 kg).
Principle of Operation **(i.e., Mechanism of Action)**	Optical Detection & Software	Optical Detection & Software
Hardware Components	Clear Guide CORE and Optical Head	Clear Guide CORE and Optical Head
Conditions of Use	Image-guided Procedures	Image-guided Procedures
Fusion Capabilities	US-CT & US-MR	US-CT & US-MR
Input Imaging Data	CT, MR, or Ultrasound	CT, MR, or Ultrasound
Device Interactions	Connected/Anchored to Transducer	Connected/Anchored to Transducer
Segmentation Process	Automatic	Automatic
Registration Process	Automatic	Automatic
Fusion Algorithms	Automatic	Automatic
Tracking/Guidance Algorithms	Automatic	Automatic
User Interface Modes	SETUP (3D), PLAN, NAVIGATION	SETUP (3D), NAVIGATION

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Category	**Modified Device:** Clear Guide SCENERGY	**Predicate Device:** Clear Guide SCENERGY
Supported Accessories (Marketed separately)	- SteriMASK transducer cover kit - VisiMARKER fiducial markers - TP Access tool with SteriGRID needle guide grid	- SteriMASK transducer cover kit - VisiMARKER fiducial markers
Intended User	Physician	Physician
Environment of Use	Clinical Setting	Clinical Setting
Duration of Use	$\leq$ 24 Hours	$\leq$ 24 Hours
Number of Uses	Reusable	Reusable
Sterility	Non-Sterile	Non-Sterile
Bench Testing	N/A (no modifications)	N/A (no modifications)
Animal Testing	N/A	N/A
Clinical Testing	Yes	Yes
Standards	N/A (for software)	N/A (for software)

The fundamental **optical detection** technology used for marker tracking and instrument guidance is unaffected by the change, and thus identical to the predicate version of **CLEAR GUIDE** SCENERGY. Similarly, the image **fusion** technology developed for the predicate **CLEAR GUIDE** SCENERGY is not modified. Instead, existing technologies for marker detection (i.e. segmentation and registration), target selection, and guidance overlay mechanisms were reused to show visualizations pertaining to the newly supported **CLEAR GUIDE** SteriGRID needle guide grid accessory on the static MR/CT images. The software takes advantage of the permanent **CLEAR GUIDE** VisiMARKER fiducial markers on the **CLEAR GUIDE** TP Access frame to accurately register it to the loaded static image volume. This static guidance information is presented on a new graphical user interface called "PLAN", which is only enabled if **CLEAR GUIDE** SCENERGY is configured for transperineal procedures. Any other changes to the technological characteristic descriptions are editorial in nature for clarity, and **subtantially equivalence** is further supported by the comparison table.

Performance Data

No new performance data were needed to evaluate the "software" device modification as the intended use, indications for use, underlying device technology, principles of operation, as well as the device components (Clear Guide CORE, Clear Guide Optical Head) were not changed. For the **CLEAR GUIDE** TP Access tool with the **CLEAR GUIDE** SteriGRID accessorry, functional tests as well as evaluation of sterility, packaging, stability, and biocompatibility were performed. The newly added "PLAN" user interface and added support for the registration of "SteriGRID" (Transperineal Guide Grid) accessory did not affect the safety and effectiveness of the device, which is supported by the execution and evaluation of well-established **CLEAR GUIDE** SCENERGY Verification and Validation (V&V) methods as part of the **CLEAR GUIDE** MEDICAL's design control activities. In addition, a small clinical testing was performed to demonstrate that **CLEAR GUIDE** SCENERGY accurately achieves its intended use.

Hardware Verification and Validation Testing

Hardware V&V tests were not performed since those components were not changed. **CLEAR GUIDE** Optical Head and **CLEAR GUIDE** CORE are in compliance with ES60601-1 and IEC 60601-1-2 standards. Necessary software/hardware integration tests with the new **CLEAR GUIDE** TP Access (with **CLEAR GUIDE** SteriGRID) acessory devices were performed.

Software Verification and Validation Testing

Software V&V testing were conducted and documented based on the risks of software functions in the context of the intended use as recommended by FDA's Guidance titled "*Content of Premarket Submissions for Device Software Functions*". For the **CLEAR GUIDE** SCENERGY, the "enhanced" documentation level was considered as appropriate, since a failure or flaw of any device software functions could present a hazardous situation with a probable risk of death or serious injury, either to a patient, user of the device, or others in the environment of use.

Clinical Testing

A small (10 patient) clinical validation study (NCT05573048, "*A Study of Optical Fusion Trans-Perineal Grid*") was run to further test the safety and effectiveness of the modifications to **CLEAR GUIDE** SCENERGY. The study validated the workflow, characterized the intervention accuracy within the existing device performance, and confirmed safety as compared to that demonstrated in experiments performed using a perineal template to facilitate needle localization for focal laser ablation of cadaveric prostate. No adverse effects or new risks were observed and **CLEAR GUIDE** SCENERGY accurately achieved its intended use throughout the study.

Conclusions

Based on the comparison presented above, therere are no differences in the product's technological characteristics with respect to the its predicate device, and therefore no new or different questions of safety or effectiveness are raised. Additionally, verification & validation tests confirm that the **CLEAR GUIDE** SCENERGY is as safe and as effective as the predicate device for the intended use. For this particular device modification, therefore, the **CLEAR GUIDE** SCENERGY is substantially equivalent to its predicate device.