Clear Guide Medical
℅ Mr. Jack Kent
Director of Regulatory Affairs and Quality Systems
3600 Clipper Mill Road, Suite 400
BALTIMORE MD 21211

September 30, 2020

Re: K201188
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
Dated: August 21, 2020
Received: August 25, 2020

Dear Mr. Kent:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201188

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 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).

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 K201188
(per 21 CFR § 807.92)

Submitter's Information

Name	Clear Guide Medical, Inc.
Address	3600 Clipper Mill Rd., Suite 400 Baltimore, MD 21211
Phone Number	(443) 602-8950
Contact Person	Jack Kent, Director of Regulatory Affairs and Quality System
Date Prepared	September 17, 2020

Device Information

Trade Name	Clear Guide SCENERGY
Common Name	System, Imaging Software
Classification	Computed Tomography X-Ray System 21 CFR § 892.1750 (Product Code JAK)

Predicate Device Information

Device Name	Clear Guide SCENERGY
510(k) Number	K171677
Common Name	System, Imaging Software
Classification	Computed Tomography X-Ray System 21 CFR § 892.1750 (Product Code JAK)

Device Description

The Clear Guide SCENERGY guidance system is intended to be an accessory to existing ultrasound imaging systems, to provide image fusion, instrument tracking, and image/instrument guidance functionality to operators during image-guided medical interventions that utilize data from multiple modalities (e.g., ultrasound and computed-tomography (CT), ultrasound and magnetic resonance (MR)). 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., new CT or MR) 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 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).

Comparison to Predicate: This indications for use statement is exactly the same as the predicate device, except for language specific to the minimum size for a patient.

Technological Characteristics

The Clear Guide SCENERGY operates using optical detection technology. The Clear Guide SCENERGY enables fusion with two difference image volumes: CT and MRI. Fusion with ultrasound is available with both types, versus just CT for the predicate device. Optical detection technology does not require specialized instruments or calibration at the point of use. As with the predicate device, the Clear Guide SCENERGY overlays instrument positioning data onto an existing ultrasound image through proprietary software algorithms. For certain software algorithms (specifically segmentation and registration), these functions are

automated. A comparison of Clear Guide SCENERGY's technological characteristics to its predicate device is provided below.

Category	Modified Clear Guide SCENERGY	Original Clear Guide SCENERGY
Product Name (Full)	Clear Guide SCENERGY	Clear Guide SCENERGY
510(k) Number	K201188	K171677
Product Code(s)	JAK	JAK
Classification Regulation	21 CFR 892.1750	21 CFR 892.1750
Regulatory Class	II	II
Intended Use	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 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).	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.
Fundamental Technology (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
Operating Principle	Optical Detection	Optical Detection
Conditions of Use	Optical Detection	Optical Detection
Fusion Capabilities	US-CT & US-MR	US-CT & US-MR

Category	Modified Clear Guide SCENERGY	Original Clear Guide SCENERGY
Signal Receiver	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
Intended User	Physician	Physician
Environment of Use	Clinical Setting	Clinical Setting
Duration of Use	≤ 24 Hours	≤ 24 Hours
Number of Uses	Reusable	Reusable
Sterility	Non-Sterile	Non-Sterile
Bench Testing	N/A (no modifications)	Yes (V&V on modification)
Animal Testing	N/A	N/A
Clinical Testing	Yes	N/A
Standards	N/A (for software)	N/A (for software)

Performance data was collected to demonstrate that the Clear Guide SCENERGY achieves its intended function in a manner that is as safe and as effective as the predicate device.

Performance Data

Performance testing of the Clear Guide SCENERGY device demonstrates that the product accurately achieves its intended use. Results of performance testing show that the subject device is as safe and as effective as the predicate device.

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for the Clear Guide SCENERGY was considered as a "moderate" level of concern, since a failure or latent flaw in the software could directly result in minor injury to the patient or operator, or indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider.

Segmentation Testing
The automatic segmentation of fiducial markers by the Clear Guide SCENERGY was evaluated by comparing software outputs to manual selection in phantom datasets.

Fusion Testing
The Clear Guide SCENERGY's ability to provide fused images from ultrasound and CT/MR modalities was evaluated using fusion testing. Fusion quality was assessed by taking distance measurements between identifiable landmarks or surfaces seen on ultrasound and CT, or ultrasound and MR. This metric is known as Tissue Registration Error (TRE).

Systematic Error (Tip-to-Tip) Testing
Systematic error in the Clear Guide SCENERGY is defined as the cumulative error that would be observed within the entire system, which includes segmentation, registration, fusion, and guidance errors. This performance metric is a "tip-to-tip" distance from the needle point seen by ground truth CT (or MR) to the same needle point seen by Clear Guide SCENERGY's displayed guidance. This metric has been called "tracking error" in literature for the predicate device. Phantom datasets were utilized for this evaluation.

Clinical Testing
A small safety study was run to demonstrate that the Clear Guide SCENERGY could be utilized safely in pediatric patients without creating new or different questions of safety or effectiveness. The study included patients ranging in age (5 to 17) and weight (11.9 to 78.9 kg) to demonstrate use in children and adolescents.

Conclusions

The Clear Guide SCENERGY has the same intended use as the predicate device, with a minor change to its indications for use. There are no differences in the product's feature offerings (from the predicate device), and therefore no new or different questions of safety or effectiveness are raised. Additionally, performance tests confirm that the Clear Guide SCENERGY is as safe and as effective as the predicate device for the intended patient population. Therefore, the Clear Guide SCENERGY is substantially equivalent to its predicate device.