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

July 31, 2020

Re: K201898
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: June 23, 2020
Received: July 2, 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)*

K201898

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.

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** K201898
(per 21 CFR § 807.92)

Submitter's Information

| | |
|---|---|
| *Name* | Clear Guide Medical, Inc. |
| *Address* | 3600 Clipper Mill Rd., Suite 400<br>Baltimore, MD 21211 |
| *Phone Number* | (443) 602-8950 |
| *Contact Person* | Jack Kent, Director of Regulatory Affairs and Quality System |
| *Date Prepared* | July 27, 2020 |

Device Information

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

Predicate Device Information

| | |
|---|---|
| *Device Name* | Clear Guide SCENERGY |
| *510(k) Number* | K171677 |

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.

*Comparison to Predicate:* This indications for use statement is exactly the same as the predicate device.

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.

This 510(k) specifically adds the CORETABLET ("CORE 13") to the hardware platform. This medical grade PC provides the necessary processing power and touchscreen inputs to properly execute the Clear Guide SCENERGY software.

| Category | Modified Clear Guide SCENERGY | Original Clear Guide SCENERGY |
|---|---|---|
| Product Name (Full) | Clear Guide SCENERGY | Clear Guide SCENERGY |
| 510(k) Number | K201898 | K171677 |
| Product Code(s) | JAK | JAK |
| Classification Regulation | 21 CFR 892.1750 | 21 CFR 892.1750 |
| Regulatory Class | II | II |
| Intended Use | Image Fusion<br>Instrument Tracking and Guidance | Image Fusion<br>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.<br><br>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. | 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.<br><br>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<br>(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 |
| Signal Receiver | Connected/Anchored to Transducer | Connected/Anchored to Transducer |
| Segmentation Process | Automatic | Automatic |
| Registration Process | Automatic | Automatic |

| Category | Modified Clear Guide SCENERGY | Original Clear Guide SCENERGY |
|---|---|---|
| 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 | Yes (V&V on modification) | Yes (V&V on modification) |
| Animal Testing | N/A | N/A |
| Clinical Testing | N/A | N/A |
| Standards | IEC 60601-1 & IEC 60601-1-2 | 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, while also showing that differences in technological features from the predicate device did not affect device performance. Results of performance testing show that the subject device is as safe and as effective as the predicate device.

### Hardware Verification and Validation Testing

Tests were completed in accordance with the CORE V&V testing plan. This includes any necessary testing to achieve compliance with IEC 60601-1 and IEC 60601-1-2 standards. Hardware testing includes component verification, system infrastructure and architecture testing, and general system operation testing.

### 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.

Conclusions

The Clear Guide SCENERGY has the same intended use as the predicate device. 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. Therefore, the Clear Guide SCENERGY is substantially equivalent to its predicate device.