DEPARTMENT OF HEALTH & HUMAN SERVICES   Public Health Service

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Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Clear Guide Medical   February 12, 2016
℅ Mr. Jack Kent
Director of Regulatory Affairs and Quality System
3600 Clipper Mill Road, Suite 400
BALTIMORE MD 21211

Re: K153004
    Trade/Device Name: Clear Guide SCENERGY
    Regulation Number: 21 CFR 892.1750
    Regulation Name: Computed tomography x-ray system
    Regulatory Class: II
    Product Code: JAK
    Dated: January 18, 2016
    Received: January 19, 2016

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
   and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number *(if known)*
K153004

Device Name
Clear Guide SCENERGY

Indications for Use *(Describe)*
The Clear Guide Scenergy is a stereotaxic accessory for the fusion of images from Computed Tomography (CT) and Ultrasound (US) modalities.

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.

510(k) Summary
(per 21 CFR § 807.92)

Submitter's Information

Name	Clear Guide Medical
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	February 10, 2016

Device Information

Trade Name	Clear Guide SCENERGY
Common Name	Computer Assisted, Image-Guided Surgery System
Classification	Computed Tomography X-Ray System
	21 CFR § 892.1750 (Product Code JAK)

Predicate Device Information

Device Name	PercuNav
510(k) Number	K132087

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 ultrasound and CT modalities. 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, and the user cannot modify either result. Segmentation results are deterministic, meaning that new inputs (e.g., a new CT) 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 (see indications for use). 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 a stereotaxic accessory for the fusion of images from Computed Tomography (CT) and Ultrasound (US) modalities.

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: The indications for use statement for the Clear Guide SCENERGY differs from the predicate device to account for technological differences and to provide additional clarity. These changes do not represent a difference in the overall intended use of the product compared to the predicate device.

Technological Characteristics

The Clear Guide SCENERGY operates using optical detection technology, instead of electromagnetic (EM) technology employed by the predicate device. Although both technologies can be used to achieve the intended use (provide image fusion, track instrumentation, and provide guidance), the 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, where the predicate device relies upon manual entry. A comparison of Clear Guide SCENERGY's technological characteristics to its predicate device is provided below.

Category	Clear Guide SCENERGY	PercuNav
Product Name (Full)	Clear Guide SCENERGY	PercuNav
510(k) Number	K153004	K132087
Product Code(s)	JAK	JAK, IYO, LLZ
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 a stereotaxic accessory for the fusion of images from Computed Tomography (CT) and Ultrasound (US) modalities. 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.	PercuNav is a stereotaxic accessory for Computed Tomography (CT), Magnetic Resonance (MR), Ultrasound (US), Positron Emission Tomography (PET), Single Photon Emission Computed Tomography (SPECT), Rotational Fluoroscopy, Endoscopy, and other imaging systems. CT, Ultrasound, PET, MR, and Rotational Fluoroscopy may be fused in various combinations, such as CT with MR, MR with ultrasound, etc. It may include instrumentation to display the simulated image of a tracked insertion tool such as a biopsy needle, guidewire or probe on a computer monitor screen that shows images of the target organs and the current and the projected future path of the interventional instrument taking into account patient movement. This is intended for treatment planning and guidance for clinical, interventional, and/or diagnostic procedures. The device also supports an image-free mode in which the proximity of the interventional device is displayed relative to another device. The device is intended to be used in interventional and diagnostic procedures in a clinical setting. The device is also intended for use in clinical interventions to determine the proximity of one device relative to another. Example procedures include, but are not limited to: […]
Fundamental Technology	Optical Detection	Electromagnetic (EM)
Signal Receiver	Connected/Anchored to Transducer	Connected/Anchored to Transducer and Instrument
Segmentation Process	Automatic	Manual
Registration Process	Automatic	Manual
Fusion Algorithms	Automatic	Automatic

Category	Clear Guide SCENERGY	PercuNav
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	Yes
Animal Testing	Yes	N/A
Clinical Testing	Yes	None
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, while also showing that differences in technological characteristics from the predicate device did not affect device performance. Results of performance testing show that the subject device, the Clear Guide SCENERGY, 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, animal, and human datasets. Segmentation error and detection rate were analyzed, with passing results (per acceptability criteria).

Registration Testing

The automatic registration of the dynamic imaging modality (ultrasound) to the static imaging modality (CT) was evaluated in terms of fiducial registration error (FRE). Using phantom, animal, and human datasets, the FRE metric was within acceptable limits, and there were no instances of misregistration.

Guidance (Tip-to-Target) Testing

Bench testing was performed to evaluate the performance of the instrument guidance feature of the Clear Guide SCENERGY. Specifically, guidance testing evaluated the end user's ability to hit a desired target, so a "tip-to-target" distance metric evaluated this performance aspect. Guidance performance (tip-to-target distance) yielded a passing test result.

Fusion Testing

The Clear Guide SCENERGY's ability to provide fused images from ultrasound and CT modalities was evaluated using fusion testing. Using phantom, animal, and human datasets, fusion quality was assessed by taking distance measurements between identifiable landmarks seen on ultrasound and CT. This metric is known as Tissue Registration Error (TRE). Multiple images per dataset were evaluated by sampling across the entire run. TRE was analyzed, with passing test results (per acceptability criteria).

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 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. For the Clear Guide SCENERGY, the total systematic error was found to be within test acceptance criteria (passing test result).

Deformation Testing

The Clear Guide SCENERGY simulates deformation of the static CT image to compensate for compression error caused by pressing the probe onto the patient tissue. Performance testing for this feature measured the estimated recovery (i.e., simulated distance from target divided by original compression error, reported as a percent). In silicone liver and in-vivo porcine datasets, percent recovery metrics demonstrated a positive effect compared to no deformation simulation.

Conclusions

The Clear Guide SCENERGY has the same intended use as the predicate device. Changes to the specific indications for use statement were made to account for technological differences, without impacting intended use. Differences in the product's technology do not raise different questions of safety or effectiveness. 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.