Weipeng (Suzhou) Medical Devices Co., Ltd.
℅ Geetha Rao, Ph.D.
Regulatory and Quality Representative
Springborne Life Sciences
750 Menlo Avenue, Suite 200
MENLO PARK CA 94025

October 7, 2020

Re: K202119
Trade/Device Name: AcuSee AS-P1000 System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO
Dated: July 24, 2020
Received: July 30, 2020

Dear Dr. Rao:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202119

Device Name
AcuSee AS-P1000 System

Indications for Use *(Describe)*
The AcuSee AS-P1000 system is indicated for augmenting the ultrasonic image of an interventional needle or needle-like rigid device, such as a biopsy needle, an aspiration needle, or ablation needle and for predicting its future path on a display, which also shows the image of a B-scan (or similar display) of a medical ultrasound imaging system. The device is intended to be used in procedures where ultrasound is currently used for visualization.

The AcuSee AS-P1000 system is intended to be used 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.

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510(k) SUMMARY

Submitter

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Date Prepared	July 15, 2020

Device Information

Trade Name	AcuSee AS-P1000 System
Common Name	Tracking or Guidance System
Product Code	IYO, Ultrasonic pulsed echo imaging system
Regulation	21 CFR 892.1560, Ultrasonic pulsed echo imaging system
Device Class	II

Predicate Information

Device Name	Clear Guide ONE
510(k) Number	K141806

Device Overview

The AcuSee AS-P1000 system is a medical device that tracks instrument positioning during ultrasound-guided procedures to provide instrument guidance to the end user. With accessories attached to the transducer probe and needle or needle-like rigid device, the AcuSee AS-P1000 system identifies and tracks the probe and the device within the field of view through optical detection technology. By coupling positioning information with the ultrasound image, the projected instrument pathway is displayed to the user for guiding instrumentation. The AcuSee AS-P1000 system is an accessory to any compatible ultrasound machine and transducer probe.

Indications for Use

The AcuSee AS-P1000 system is indicated for augmenting the ultrasonic image of an interventional needle or needle-like rigid device, such as a biopsy needle, an aspiration needle, or ablation needle, and for predicting its future path on a display, which also shows the image of a B-scan (or similar display) of a medical ultrasound imaging system. The device is intended to be used in procedures where ultrasound is currently used for visualization.

The AcuSee AS-P1000 system is intended to be used in a clinical setting.

Technological Characteristics

The AcuSee AS-P1000 System applies optical tracking technology to augment the ultrasonic image of an interventional needle or needle-like rigid device and for predicting its future path on a display and also show the image of a B-scan (or similar display) of a medical ultrasound imaging system. The relative position and trajectory of the needle is calculated using stereo-vision optical detection of markers on tracking mounts attached to the ultrasound probe and needle device.

Device Comparison Table

Feature	Subject Device AcuSee AS-P1000 System	Predicate Device Clear Guide One	SE Comparison/ Comment
510(k) Number	NA	K141806	NA
Product Code	IYO	IYO	Same
Regulation No.	892.1560	892.1560	Same
Risk Class	II	II	Same
Regulatory Pathway	510(k)	510(k)	Same
Indications for Use	The AcuSee AS-P1000 System is indicated for augmenting the ultrasonic image of an interventional needle or needle-like rigid device, such as a biopsy needle, an aspiration needle, or ablation needle, and for predicting its future path on a display, which also shows the image of a B-scan (or similar display) of a medical ultrasound imaging system. The device is intended to be used in procedures where ultrasound is currently used for visualization.	The Clear Guide ONE is indicated for augmenting the ultrasonic image of an interventional needle or needle-like rigid device, such as a biopsy needle, an aspiration needle, or ablation needle, and for predicting its future path on a display, which also shows the image of a B-scan (or similar display) of a medical ultrasound imaging system. The device is intended to be used in procedures where ultrasound is currently used for visualization.	Identical
Intended Users	Physician	Physician	Same
Use Environment	Clinical Setting	Clinical Setting	Same
Sterility	Non-Sterile	Non-Sterile	Same
Movability	Main system mounted on movable cart	Main system mounted on movable cart	Same

Feature	Subject Device AcuSee AS-P1000 System	Predicate Device Clear Guide One	SE Comparison/ Comment
Fundamental Technology	Optical Detection	Optical Detection	Same
Device Form Factor	Main system contains camera, and PC with software on movable cart, with power cord for AC power, Separate tracking accessories consist of tracking mounts	Main system (Clear Guide Core) contains hardware and software with power adapter and cord, Separate tracking accessories include camera (Clear Guide SuperProbe) and custom instruments	Similar primary concept with different physical configuration
Detection Mechanism	Camera located at a distance tracks custom tracking mounts on ultrasound probe and needle	Camera is directly mounted on ultrasound probe and tracks custom needle	Similar concept, with a variant spatial geometry
Tracking Algorithm	Automatic	Automatic	Similar
Timing for tracking	Real-time	Real-Time	Same
Information Displayed	Overlay of the detected instrument positioning and projected path onto the ultrasound image	Overlay of the detected instrument positioning and projected path onto the ultrasound image	Same
Reusability	Reusable main system with consumable tracking mounts	Reusable main system and probe with consumable tracking needle	Similar
Instruments tracked	Any compatible needle-like instrument	Requires custom needle (not known what kind of needle)	Similar
Tracking of instrument tip	Any compatible instrument	Only with custom instrument with CLEAR GUIDE PercepTIP	Similar
Compatibility with probe	Tracking mount fits any compatible probe	Optical head with camera fits any compatible probe	Same functionality
Tracking instruments in and out-of-plane	Within +/- 90 deg	Within +/- 45 deg	Subject device has wider performance range

Feature	Subject Device AcuSee AS-P1000 System	Predicate Device Clear Guide One	SE Comparison/ Comment
Electrical Safety and Electromagnetic Compatibility	IEC 60601-1:2005+A1:2012 - Medical electrical equipment – Part 1: General requirements for basic safety and essential performance IEC 60601-1-2:2014 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.	IEC 60601-1 3rd Edition: Medical Electrical Equipment; Part 1 General Requirements for Safety IEC 60601-1-2 :2007 – Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility	Similar - Subject device meets updated standard
Performance Testing	Bench testing	Bench testing	Similar
Animal Testing	None	None	Same
Clinical Testing	None	None	Same

Substantial Equivalence Overview

The AcuSee AS-P1000 System has the same intended use and indications for use, as well as similar technological characteristics and principles of operation compared to the previously legally cleared predicate device: Clear Guide ONE (K141806, cleared in 2014).

The AcuSee AS-P1000 System and the predicate device both apply the same optical detection technology in a similar device form factor. The AcuSee AS-P1000 system overlays the detected instrument positioning data onto an existing ultrasound image through proprietary software algorithms, In the same manner as the predicate device. Both devices track targeted instrumentation and provide real-time visual guidance during a clinical procedure. Both devices have reusable main components and some consumable accessories. The AcuSee AS-P1000 System was tested to demonstrate compliance to the same applicable safety standards as the predicate device, but for updated versions of the standards.

The AcuSee AS-P1000 System uses the same primary concept for the detection mechanism but uses a different physical configuration for the camera and tracked targets, resulting in a different spatial geometry. This variation does not alter the fundamental mechanism and raises no new questions of safety. Performance data was collected to demonstrate that the AcuSee AS-P1000 system achieves its intended function in a manner that is as effective as the predicate device.

The AcuSee AS-P1000 system uses tracking mounts that are designed to fit ultrasound probes and instruments that are available on the market. Although specific models of probes (and the associated ultrasound machines with which they are used) and instruments are individually validated to be compatible, the mounts themselves are standardized and may be used with any compatible probe or instrument. Hence unlike the predicate device, the system does not require special patterns to be marked or printed to the shaft of the needle or other tracked instrument.

Although there are minor differences in technological characteristics of the AcuSee AS-P1000 System, they do not raise new issues of safety or effectiveness.

Summary of Performance Testing

The performance testing for the AcuSee AS-P1000 System includes software verification/validation testing, system verification/validation testing, bench testing and testing to compliance standards for electrical and electromagnetic safety. Traceability has been documented between the system specification to verification/validation protocols. The results of performance testing show that the AcuSee AS-P1000 system is as safe and as effective as the predicate device.

The AcuSee AS-P1000 system complies with the following recognized consensus standards:

1. IEC 60601-1:2005+A1:2012 (Medical electrical equipment – Part 1: General requirements for basic safety and essential performance).
2. IEC 60601-1-2:2014 (Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests).

Conclusion

The performance of the AcuSee AS-P1000 System is substantially equivalent to that of the Clear Guide ONE system and raises no safety or effectiveness issues and performs as well or better than the predicate device.