DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

April 21, 2017

Philips Ultrasound Inc.
% Mark Job
Regulatory Technology Services, LLC
1394 25th Street, Nw
Buffalo, Minnesota 55313

Re: K170716
Trade/Device Name: PercuNav Image Fusion and Interventional Navigation
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK, IYO, LLZ
Dated: April 5, 2017
Received: April 12, 2017

Dear Mark Job:

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,

For

Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170716

Device Name
PercuNav Image Fusion and Interventional Navigation

Indications for Use *(Describe)*
The PercuNav system is a stereotaxic accessory for computed tomography (CT), magnetic resonance (MR), ultrasound (US), and positron emission tomography (PET). CT, Ultrasound, PET, and MR may be fused in various combinations, such as CT with MR, MR with ultrasound, and so on. It may include instrumentation to display the simulated image of a tracked insertion tool such as a biopsy needle 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. The PercuNav system is intended for treatment planning and guidance for clinical, interventional, or diagnostic procedures. The PercuNav system also supports an image-free mode in which the proximity of the interventional device is displayed relative to another device.

The PercuNav system is intended to be used in interventional and diagnostic procedures in a clinical setting. The PercuNav system 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, the following:
- Image fusion for diagnostic clinical examinations and procedures
- Soft tissue biopsies (liver, lung, kidney, breast, pancreas, bladder, adrenal glands, lymph node, mesentery, and so on.)
- Soft tissue ablation (liver, kidney, breast, pancreas, lung, and so on)
- Bone ablations
- Bone biopsies
- Nerve blocks and pain management
- Drainage placements
- Tumor resections

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

This summary of safety and effectiveness information is submitted in accordance with 21CFR §807.92

1) Submitter's name, address, telephone number, contact person.

Philips Ultrasound, Inc.
22100 Bothell Everett Hwy
Bothell, WA 98021-8431

Contact person: Peng Cui,
Regulatory Affairs Specialist
Email: peng.cui@philips.com
Tel: (978) 659-7966
Fax: (978) 487-4450

Date prepared: April 18, 2017

2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/usual name: Computer assisted, image-guided surgery system
Proprietary name: PercuNav Image Fusion and Interventional Navigation

Classification Name: Computed Tomography X-ray System
Class II as described in 21 CFR 892.1750
Primary Product Code: JAK
Secondary Product Codes: IYO, LLZ

3) Substantially Equivalent Device

Philips Ultrasound believes the proposed **PercuNav Image Fusion and Interventional Navigation (**referred to as PercuNav in this summary**)** is substantially equivalent to the currently marketed Philips PercuNav (K132087).

4) Device Description

The proposed **PercuNav** provides image-guided diagnostic and intervention that enables fusion of diagnostic images and guidance of tracked instruments to physician-defined targets. The target can be indicated either pre-procedurally or intra-procedurally, either using images or relative to an indicated position on the patient.

The proposed **PercuNav** provides real-time, three-dimensional visualization and navigation tools for all stages of diagnosis and intervention, including pre-procedure planning and procedure navigation. The system transforms two-dimensional patient

images into dynamic representations that can be fused with live ultrasound or other previously acquired images. Those two-dimensional patient images, or scan sets, are derived from Ultrasound, CT, PET, PET/CT, and MRI. The resulting dynamic representation supports diagnostic review and instrument navigation.

The PercuNav system performs spatial mapping from one image space to another image space or from image space to physical space (registration), allowing the physician to correlate scan sets with each other and to the patient. The system facilitates minimally invasive diagnostic and interventional procedures.

Features include the following:

- **Multiple Applications**: The PercuNav system supports multiple applications and can be used for ablations, biopsies, and other diagnostic and guidance procedures.
- **Multiple Modalities**: The PercuNav system works with images from multiple modalities, including but not limited to CT, MR, PET, and ultrasound.

5) Indications for Use

The PercuNav system is a stereotaxic accessory for computed tomography (CT), magnetic resonance (MR), ultrasound (US), and positron emission tomography (PET). CT, Ultrasound, PET, and MR may be fused in various combinations, such as CT with MR, MR with ultrasound, and so on. It may include instrumentation to display the simulated image of a tracked insertion tool such as a biopsy needle 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. The PercuNav system is intended for treatment planning and guidance for clinical, interventional, or diagnostic procedures. The PercuNav system also supports an image-free mode in which the proximity of the interventional device is displayed relative to another device.

The PercuNav system is intended to be used in interventional and diagnostic procedures in a clinical setting. The PercuNav system 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, the following:

- Image fusion for diagnostic clinical examinations and procedures
- Soft tissue biopsies (liver, lung, kidney, breast, pancreas, bladder, adrenal glands, lymph node, mesentery, and so on.)
- Soft tissue ablation (liver, kidney, breast, pancreas, lung, and so on)
- Bone ablations
- Bone biopsies
- Nerve blocks and pain management
- Drainage placements
- Tumor resections

6) **Technological comparison to predicate device**

The technological characteristics of the proposed PercuNav are essentially the same as those included in the currently cleared and marketed PercuNav (K132087), except the addition of the auto MR/ultrasound registrations.

Table 1: System Comparison to the Predicate device

Table 1 Comparison of the proposed **PercuNav** to the currently marketed Philips PercuNav		
Comparative Characteristics	**PercuNav (K132087) (Predicate Device)**	**PercuNav (Proposed Device)**
Indications for use	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: • Image fusion for diagnostic clinical examinations and procedures • Soft tissue biopsies (liver, lung, kidney, breast, pancreas, bladder,	The PercuNav system is a stereotaxic accessory for computed tomography (CT), magnetic resonance (MR), ultrasound (US), and positron emission tomography (PET). CT, Ultrasound, PET, and MR may be fused in various combinations, such as CT with MR, MR with ultrasound, and so on. It may include instrumentation to display the simulated image of a tracked insertion tool such as a biopsy needle 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. The PercuNav system is intended for treatment planning and guidance for clinical, interventional, or diagnostic procedures. The PercuNav system also supports an image-free mode in which the proximity of the interventional device is displayed relative to another device. The PercuNav system is intended to be used in interventional and diagnostic procedures in a clinical setting. The PercuNav system 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, the following: • Image fusion for diagnostic clinical examinations and procedures • Soft tissue biopsies (liver, lung, kidney, breast, pancreas, bladder, adrenal glands, lymph node, mesentery, and so on.) • Soft tissue ablation (liver, kidney, breast, pancreas, lung, and so on) • Bone ablations • Bone biopsies • Nerve blocks and pain

	adrenal glands, lymph node, mesentery, etc.) • Soft tissue ablation (liver, kidney, breast, pancreas, lung, etc.) • Bone ablations • Bone biopsies • Nerve Blocks & Pain Management • Drainage placements • **Hydrodissections** • **Bladder Stimulation** • **Fiducial placements** • Tumor resections • **Sinus procedures** • **Intranasal procedures** • **Transphenoidal procedures**	management • Drainage placements • Tumor resections Note: The proposed PercuNav no longer supports the bold features of the Predicate PercuNav (K132087).
Patient contact Materials	No change since K132087	
Registration methods	• Manual registrations	• Manual registrations • Automatic registration (CT/Ultrasound and MR/Ultrasound) •
Tracked Instrumentation/accessory	• Patient tracker • Ultrasound tracker • Coaxial needle tracker (CNT) • Adaptive needle tracker (ANT) • Button probes • Biopsy and RFA Introducers	Same with addition of eTrax* *eTrax has been cleared and marketed by CIVCO Medical (K092619).

Table 2: Registration Feature Comparison

Table 2 Comparison for PercuNav Registration feature to eSieFusion on Siemens ACUSON S3000 Ultrasound System		
Comparative Characteristics	**eSieFusion on Siemens ACUSON S3000 Ultrasound System (Reference)**	**PercuNav Registration (Proposed)**
Clearance status	K122825, K130739, and K152369	NO
Intended use	To align live ultrasound images with previously acquired CT images	To align live ultrasound images with previously acquired CT or MR images
Registration methods	• Manual • Automatic	• Manual • Automatic

7) Nonclinical Performance Data

Philips Ultrasound performed the following testing to ensure the safety and effectiveness of the proposed PercuNav:

- Software verification and validation – To ensure the proposed **PercuNav** meets the specifications and user needs.
- Non-Clinical Performance Data -- The accuracy test was done for the liver vessel and liver surface auto registrations. The accuracy was determined using the Target Registration Error (TRE) and was compared to an existing manual registration method available on the currently cleared PercuNav (K132087). The test results show the auto registrations' accuracy is as good as that of the manual registration.
- Non-Clinical Tests
    - AAMI / ANSI /ES60601-1:2005/(R) 2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 (consolidated text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance.
    - IEC 60601-1-2 Edition 3: 2007-03, Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
    - AAMI / ANSI / IEC 62304:2006, Medical Device Software - Software Life Cycle Processes
    - AAMI / ANSI / ISO 10993-1:2009/(R) 2013, Biological Evaluation of Medical devices - part 1: Evaluation and Testing Within A Risk Management Process
    - ISO 11135 Second Edition 2014, Sterilization of Health-care Products - Ethylene Oxide - Requirements For The Development, Validation And Routine Control Of A Sterilization Process For Medical Devices
    - AAMI ANSI ISO 11607-1:2006/(R)2010, Packaging For Terminally Sterilized Medical Devices - Part 1: Requirements For Materials, Sterile Barrier Systems And Packaging Systems [Including: Amendment 1 (2014)]
    - AAMI ANSI ISO 11607-2:2006/(R)2010, Packaging For Terminally Sterilized Medical Devices - Part 2: Validation Requirements For Forming, Sealing And Assembly Processes [Including: Amendment 1 (2014)]

- Quality assurance measures applied to the system design and development include, but were not limited to:
    - Risk Analysis
    - Product Specifications
    - Design Reviews
    - Verification and Validation

8) Clinical Data

The **proposed PercuNav** did not require clinical study, since substantial equivalence to the currently marketed predicate devices; Philips PercuNav (K132087) was demonstrated with the following attributes:

- Design features;
- Indication for use;
- Fundamental scientific technology;
- Non-clinical performance testing; and
- Safety and effectiveness.

9) Conclusion

Based on the conformance to standards, development under Philips Ultrasound's quality system, and the successful verification and the performance testing, Philips Ultrasound believes that the proposed **PercuNav** is substantially equivalent to the predicate device Philips PercuNav (K132087). The proposed **PercuNav** has different technological characteristics such as auto liver vessel and surface registrations but these differences do not raise new questions of safety and effectiveness. The performance test data demonstrates the auto registrations' accuracy is as good as that of the existing manual registration available on the currently cleared PercuNav (K132087). Therefore, the proposed **PercuNav** is as safe and effective as the currently marketed and predicate device, Philips PercuNav (K132087), without raising any new safety and/or effectiveness concerns.