January 18, 2023

Philips Ultrasound LLC
% Prithul Bom
Official Correspondent
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
SAINT PAUL, MN 55114

Re: K223804
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: December 16, 2022
Received: December 19, 2022

Dear Prithul Bom:

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,

Lu Jiang 2023.01.18 16:02:43 -05'00'

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Imaging Devices and Electronic Products
OHT8: Office of 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)*
K223804

Device Name
PercuNav Image Fusion and Interventional Navigation System

Indications for Use *(Describe)*
The PercuNav Image Fusion and Interventional Navigation System is a stereotaxic accessory for computed tomography (CT), cone beam CT (CBCT), 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 Image Fusion and Interventional Navigation System is intended for treatment planning and to assist guidance for clinical, interventional, or diagnostic procedures in a clinical setting.

The PercuNav Image Fusion and Interventional Navigation System is also intended to supplement live imaging in clinical interventions to determine the proximity of one device relative to another.

The PercuNav Image Fusion and Interventional Navigation System is not intended to be the sole guidance for any procedure. Procedures that can be guided by the PercuNav Image Fusion and Interventional Navigation System adjunctively include, but are not limited to, the following:
- Image fusion for diagnostic clinical examinations and procedures
- Soft tissue biopsies
- Soft tissue ablation
- Bone ablation
- Bone biopsies
- Nerve blocks and pain management
- Drainage placements

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 K223804

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

Date Prepared: December 12, 2022

I. Submitter

Manufacturer Name and Address

Philips Ultrasound LLC
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II. Device

Proprietary Name

PercuNav Image Fusion and Interventional Navigation System

Regulation Description

Classification Description	21 CFR Section	Product Code
System, X-Ray, Tomography, Computed	892.1750	JAK
System, Imaging, Pulsed Echo, Ultrasonic	892.1560	IYO
System, Image Processing, Radiological	892.2050	LLZ

Device Class

Class II

Review Panel

Radiology

Predicate Device

PercuNav Image Fusion and Interventional Navigation (K201053, cleared May 14, 2020)

III. Overview

The PercuNav Image Fusion and Interventional Navigation System provides image-guided diagnostic and intervention support 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 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.

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The purpose of this Traditional 510(k) is to introduce the user-assisted Ablation Planning and Co-Registration workflow enhancements to the PercuNav Image Fusion and Interventional Navigation System.

Manual Ablation Planning and Co-Registration features are available on the currently marketed PercuNav Image Fusion and Interventional Navigation System. The predicate manual versions mean that the user must do all the registration and ablation planning from the start, there is no proposed starting point. These proposed changes allow implementation of the user-assisted version of each software feature to enhance the workflow by proposing an option to the user that they then can manipulate or accept .

IV. Device Description

The user-assisted Ablation Planning software tool enhancement is to aid the user when placing the ablation tip using a computer algorithm to maximize the spatial overlap between the ablation zone volume and the tumor contour.

The user-assisted Co-Registration software tool is to aid the user in co-registering between two different CT series from the same patient using a computer algorithm to create an image that forms the basis to be applied to the various CT sets for landmark registration.

V. Indications for Use

The PercuNav Image Fusion and Interventional Navigation System is a stereotaxic accessory for computed tomography (CT), cone beam CT (CBCT), 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 Image Fusion and Interventional Navigation System is intended for treatment planning and to assist guidance for clinical, interventional, or diagnostic procedures in a clinical setting.

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- Soft tissue ablation
- Bone ablation
- Bone biopsies
- Nerve blocks and pain management
- Drainage placements

VI. Comparison of Technological Characteristics with the Predicate

The purpose of the submission is to introduce the user-assisted Ablation Planning and Co-Registration enhancements:

- Predicate (K201053): Manual ablation zone and merging of images

- Proposed: Workflow enhancement that presents an ablation zone (user-assisted Ablation Planning) and merged images that can be adjusted and/or accepted based on User's clinical judgement (user-assisted Co-Registration).

The intended users, use environment, indications for use, intended use, accessories and offered features are unchanged as compared to the predicate.

VII. Nonclinical Performance Data

The proposed PercuNav Image Fusion and Interventional Navigation System was tested in accordance with Philips internal processes. Design Control activities to assure the safe and effective performance of the PercuNav Image Fusion and Interventional Navigation System software features include but are not limited to the following:

- Requirements Review
- Risk Analysis and Management
- Product Specifications
- Design Reviews

Non-clinical bench performance testing was also conducted for the proposed user-assisted Ablation Planning and Co-Registration enhancements.

Biocompatibility testing is not needed for the introduction of the user-assisted Ablation and Co-Registration enhancements to the Image Fusion and Interventional Navigation System as the patient contacting accessories are not impacted by the introduction of the proposed software enhancements.

VIII. Clinical Data

The proposed PercuNav Image Fusion and Interventional Navigation System did not require clinical data for determination of substantial equivalence since substantial equivalence was demonstrated based on the following attributes:

- Design features
- Indications for use
- Fundamental scientific technology
- Non-clinical performance testing

IX. Conclusion

For feature testing, all pre-determined acceptance criteria were met. Results of these tests show that the proposed PercuNav Image Fusion and Interventional Navigation System meets its intended use.

The predicate, PercuNav Image Fusion and Interventional Navigation (K201053), includes Manual Ablation Planning and Co-Resignation features. The addition of user-assisted enhancement does not significantly affect the use of the software, nor introduce any new or significantly modified risks. The differences between the proposed software and predicate software do not raise new questions of safety and/or effectiveness. Therefore, the proposed PercuNav Image Fusion and Interventional Navigation System is similar to the predicate PercuNav Image Fusion and Interventional Navigation (K201053) in terms of indications for use, design, technological characteristics, modes of operations, safety and effectiveness.