Philips Ultrasound, Inc.
% Prithul Bom
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
SAINT PAUL MN 55114

May 14, 2020

Re: K201053
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 20, 2020
Received: April 21, 2020

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,

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)*
K201053

Device Name
PercuNav Image Fusion and Interventional Navigation

Indications for Use *(Describe)*
The PercuNav 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 system is intended for treatment planning and to assist guidance for clinical, interventional, or diagnostic procedures in a clinical setting.

The PercuNav system is also intended to supplement live imaging in clinical interventions to determine the proximity of one device relative to another.

The PercuNav system is not intended to be the sole guidance for any procedure. Procedures that can be guided by the PercuNav 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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Section 8: 510(k) Summary

K201053

Philips PercuNav Image Fusion and Interventional Navigation System

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

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

Sponsor:
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Secondary Contact:
Hebe Sun
Senior Manager, Regulatory Affairs

Date Prepared
January 28, 2020

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

Proprietary Name:
PercuNav Image Fusion and Interventional Navigation System

Common Name:
PercuNav Image Fusion and Interventional Navigation System
Computed Tomography X-ray System

Regulation Description:

Classification Description	21 CFR Section	Product Code
Computed Tomography X-ray System	892.1750	JAK
Ultrasound Pulsed Echo Imaging System	892.1560	IYO
Picture Archiving and Communications System (PACS)	892.2050	LLZ

As stated in 21 CFR, parts 892.1750, 892.1560, and 892.2050, each of these generic types of devices have been classified as Class II.

Device Class:
Class II

3. Indications for Use

The PercuNav 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 system is intended for treatment planning and to assist guidance for clinical, interventional, or diagnostic procedures in a clinical setting.

The PercuNav system is also intended to supplement live imaging in clinical interventions to determine the proximity of one device relative to another.

The PercuNav system is not intended to be the sole guidance for any procedure. Procedures that can be guided by the PercuNav 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

4. Device Description

The Philips PercuNav Image Fusion and Interventional Navigation System 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 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 purpose of this Traditional 510(K) Pre-market Notification is to introduce a new semi-automated visualization tool entitled “Tumor Contouring” to the current PercuNav software system. The Tumor Contouring visualization tool is designed to aid the end user in the planning and targeting of lesions, structures, and other regions of interests prior to an interventional procedure, soft tissue ablation, etc. The Tumor Contouring tool allows the end user to generate and modify a 3D contour around a region or soft tissue structure of interest and then this contour, once accepted by the user, can be visualized and dynamically reformatted and fused in various imaging combinations for later procedures.

5. Substantially Equivalent Devices

Primary Predicate Device

Philips PercuNav Image Fusion an Interventional Navigation System	K170716	April 21, 2017

Reference Predicate Device

Philips QLAB Advanced Quantification Software (GI 3 DQ)	K191647	December 20, 2019
Veran Medical Technologies IG 4 Image Guided Software	K093995	January 27, 2010

6. Technological Comparison to Predicate Devices

The PercuNav Image Fusion and Interventional Navigation System with the addition of the Tumor Contouring visualization tool has the same intended use and similar technological characteristics as the legally marketed primary PercuNav predicate device. A comparison of the proposed PercuNav System (including the Tumor Contouring visualization tool) to the currently marketed predicate PercuNav device and the reference predicates Philips QLAB System (GI 3 DQ application) and Veran Medical Technologies IG 4 Image Guided Software are provided in the table below:

Table 8.1: Comparison of Subject Philips PercuNav Image Fusion and Interventional Navigation to the predicate Philips PercuNav Image Fusion and Interventional Navigation, QLAB Advanced Quantification Software (GI 3DQ Application) and Veran Medical Technologies IG 4 Image Guided System.

	Subject Device	**Predicate Device**	**Reference Predicate Device**	**Reference Predicate Device**	**Explanation of Differences**
Manufacturer	Philips Ultrasound, Inc.	Philips Ultrasound, Inc.	Philips Ultrasound, Inc.	Veran Medical Technologies	None
Trade Name	PercuNav System	PercuNav System	QLAB System	IG 4 Image Guided System	None
Feature	Tumor Contouring Visualization Tool	PercuNav Software	QAPP – GI 3DQ	IG 4 Software	None
510(k) Number	Pending	K170716	K191647	K093995	None
Regulation Number	21 CFR 892.1750	21 CFR 892.1750	21 CFR 892.2050	21 CFR 892.1750	Regulation Number, Regulation Name, Classification, and Product Code are identical between subject device and primary predicate device.
Regulation Name	Computed tomography x-ray system	Computed tomography x-ray system	System, Image processing, Radiological - Picture Archiving and Communications System (PACS)	Computed tomography x-ray system	
Classification	Class II	Class II	Class II	Class II	
Product Code(s)	JAK, IYO, LLZ	JAK, IYO, LLZ	LLZ	JAK	
Indications for Use	The PercuNav 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 system is intended for treatment planning and to assist	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	QLAB Quantification software is a software application package. It is designed to view and quantify image data acquired on Philips ultrasound systems.	The ig4™ Image Guided System is a stereotactic accessory for Computed Tomography (CT) or 3D fluoroscopic x-ray systems. The ig4 System is indicated for displaying an interventional instrument such as a biopsy needle, an aspiration needle, or ablation needle on a computer monitor that also displays CT-based or 3D fluoroscopic x-ray based model of the target organ(s). The ig4™ System is additionally indicated for overlaying Ultrasound images onto the model of the target organ(s). The ig4™ System compensates for the patient's respiratory phases.	The Indications for Use of the subject PercuNav System and the primary predicate PercuNav System are the same and have not fundamentally changed from the previous clearance of this system. The PercuNav and QLAB System are similar in regards to image display and quantification purposes to the end user. Additionally, the subject PercuNav System and the Veran ig4 System also share similar indications for use in regards to visualization technologies being used for procedural planning and instrument focused interventions. Moreover, the Veran ig4 System is indicated for use

	Subject Device	Predicate Device	Reference Predicate Device	Reference Predicate Device	Explanation of Differences
Manufacturer	Philips Ultrasound, Inc.	Philips Ultrasound, Inc.	Philips Ultrasound, Inc.	Veran Medical Technologies	None
Trade Name	PercuNav System	PercuNav System	QLAB System	IG 4 Image Guided System	None
Feature	Tumor Contouring Visualization Tool	PercuNav Software	QAPP – GI 3DQ	IG 4 Software	None
	guidance for clinical, interventional, or diagnostic procedures in a clinical setting. The PercuNav system is also intended to supplement live imaging in clinical interventions to determine the proximity of one device relative to another. The PercuNav system is not intended to be the sole guidance for any procedure. Procedures that can be guided by the PercuNav 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	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		The ig4™ System is intended for use in clinical interventions and for anatomical structures where computed tomography, 3D fluoroscopic x-ray, or ultrasound are currently used for visualizing such procedures.	with 3D fluoroscopic x-ray systems, which is a term that is synonymous with Cone Beam CT imaging acquisition.
System Components	• Field Generator (FG)	• Field Generator (FG)	The sole component of the	• EM tracking	The System Components of

	Subject Device	Predicate Device	Reference Predicate Device	Reference Predicate Device	Explanation of Differences
Manufacturer	Philips Ultrasound, Inc.	Philips Ultrasound, Inc.	Philips Ultrasound, Inc.	Veran Medical Technologies	None
Trade Name	PercuNav System	PercuNav System	QLAB System	IG 4 Image Guided System	None
Feature	Tumor Contouring Visualization Tool	PercuNav Software	QAPP – GI 3DQ	IG 4 Software	None
	• Tool Connection Unit (TCU) • PercuNav Software • Instrumentation	• Tool Connection Unit (TCU) • PercuNav Software • Instrumentation	QLAB System is a software platform with individually designated QAPPs (i.e. GI 3 DQ, etc.).	accessory for needles and ultrasound probes • Patient referencing system • EM Field Generator and Tracking System • Ig4 software	the subject PercuNav System and the primary predicate PercuNav System are identical and have not been changed from the previous clearance of this system. As mentioned, the scope of this submission is to introduce modifications to the PercuNav Software in releasing the Tumor Contouring visualization tool. The subject PercuNav and the predicate IG4 Systems are similar in regards to the system components including technologies to facilitate instrumentation tracking.
Tracked Instrumentation / Accessories	• Patient Tracker • Ultrasound Tracker • Coaxial Needle Tracker (CNT) • Adaptive Needle Tracker (ANT) • Button Probes • Biopsy and RFA Introducers	• Patient Tracker • Ultrasound Tracker • Coaxial Needle Tracker (CNT) • Adaptive Needle Tracker (ANT) • Button Probes • Biopsy and RFA Introducers	The sole component of the QLAB System is a software platform with individually designated QAPPs (i.e. GI 3 DQ, etc.).	• EM Tracking accessory for needles and ultrasound probes • Patient Referencing System	The Instrumentation / Accessories of the subject PercuNav System and the primary predicate PercuNav System are identical and have not been changed from the previous clearance of this system. As mentioned, the scope of this submission is to introduce modifications to the PercuNav Software in releasing the Tumor Contouring visualization tool. The subject PercuNav and the

		Subject Device	Predicate Device	Reference Predicate Device	Reference Predicate Device	Explanation of Differences
Manufacturer		Philips Ultrasound, Inc.	Philips Ultrasound, Inc.	Philips Ultrasound, Inc.	Veran Medical Technologies	None
Trade Name		PercuNav System	PercuNav System	QLAB System	IG 4 Image Guided System	None
Feature		Tumor Contouring Visualization Tool	PercuNav Software	QAPP – GI 3DQ	IG 4 Software	None
						predicate IG4 System include similar tracked instrumentation and accessories in order to track needles and/or US probes in the tracking environment.
Software Design	Tool / Application Description	Visualization tool generates semi-automated anatomic border detection based on greyscale differentiation. The tool generates a preliminary border that the user must modify and review. This tool computes and presents the volume of the contour to the end user.	Transforms two-dimensional patient images (Ultrasound, CT, PET, PER/CT, and MRI) into dynamic representation that can be fused with live ultrasound or other previously acquired images. The resulting dynamic representation supports diagnostic review and instrument navigation within tracking volume produced by the Field Generator.	Manual anatomic border tracing then generates automated 3D volume measurement. Diameter measurements are manually. This app computes linear measurements, area measurements, stacked contour volume measurements, and ellipsoid volume measurements.	The ig4™ Image Guided System utilizes electromagnetic tracking technology to locate and navigate instruments relative to a CT-based or 3D fluoroscopic x-ray based model of the patient anatomy. The system software allows additional data overlay of real-time Ultrasound images onto the model of the patient anatomy.	The Tumor Contouring tool provides the end user with similar functionality as the GI 3DQ application as both allow the user to generate a border or contour around the region of interest. The Tumor Contouring tool is an extension of the PercuNav Software in that it relies on the PercuNav software to generate a 3D volume for the user. Unlike the GI 3DQ application, the Tumor Contouring Tool provides a preliminary contour based on grey scale differentiation to the end user and is considered to be semi-automated. However, both the Tumor Contouring tool and GI 3 DQ, require the user to modify and confirm the contour before it is accepted. The predicate IG4 System provides similar visualization functionality to the subject PercuNav system.

		Subject Device	Predicate Device	Reference Predicate Device	Reference Predicate Device	Explanation of Differences
Manufacturer		Philips Ultrasound, Inc.	Philips Ultrasound, Inc.	Philips Ultrasound, Inc.	Veran Medical Technologies	None
Trade Name		PercuNav System	PercuNav System	QLAB System	IG 4 Image Guided System	None
Feature		Tumor Contouring Visualization Tool	PercuNav Software	QAPP – GI 3DQ	IG 4 Software	None
	Contour Generation	Preliminary borders and 3D contour are created semi-automatically based on grey scale differentiation and then the user is required to edit, accept, or reject contours. As the contour is being generated, software displays volume measurements for the selected contour.	The ability to generate a contour does not exist in the predicate device and is the subject of the present submission.	Preliminary borders are created manually by end user to create a 3D model and the user is then required to edit, accept or reject contours.	The ability to generate a contour is not clearly mentioned as part of this technology and is unknown if this functionality exists	The Tumor Contouring tool and the GI 3DQ application both allow the user to create a contour around a specified region of interest. The difference is that the Tumor Contouring tool is considered to be semi-automated in that the tool utilizes grey scale differentiation to generate an initial contour whereas the GI 3DQ requires the user to manually create the contour. However, both the Tumor Contouring tool and the GI 3DQ application require that the end user review and modify the contour, either at individual points or the overall area of the contour itself, prior to accepting the generated contour.
	Quantification Technology	Semi-automated contour generation, by which the software produces a preliminary contour trace and then the user must edit and accept contour, within the tracking volume. Creates 3D mesh to derive volume measurement of the contour generated.	The predicate PercuNav Software does not produce or derive any quantifiable measurements related to the images.	Manual border tracing over multiple slices; Creates 3D mesh to derive volume measurement; diameter measurement done via manual distance measurement tool	The quantification technology is not clearly mentioned as part of this technology and is unknown if this technology exists.	The Tumor Contouring visualization tool is a semi-automated tool that produces a contour around a region based on grey scale differentiation whereas the GI 3DQ application utilizes a manual contour to be generated by the end user. However, both the Tumor

		Subject Device	Predicate Device	Reference Predicate Device	Reference Predicate Device	Explanation of Differences
Manufacturer		Philips Ultrasound, Inc.	Philips Ultrasound, Inc.	Philips Ultrasound, Inc.	Veran Medical Technologies	None
Trade Name		PercuNav System	PercuNav System	QLAB System	IG 4 Image Guided System	None
Feature		Tumor Contouring Visualization Tool	PercuNav Software	QAPP – GI 3DQ	IG 4 Software	None
						Contouring tool and the GI 3DQ application create and utilize the 3D mesh to derive measurements for the region of interest. The Tumor Contouring tool only produces the volume of the contour for the end user.

7. Non-Clinical Testing

The proposed software modifications (the introduction of the Tumor Contouring visualization tool) to the subject Philips PercuNav System were tested in accordance with Philips internal processes. Successful completion of the prescribed verification testing support the proposed modification to the PercuNav System software relative to the currently marketed unmodified PercuNav System.

Design Control activities to assure the safe and effective performance of the modified PercuNav System software / Tumor Contouring visualization tool include but are not limited to the following:

- Software Verification – Standard verification testing in order to ensure the proposed PercuNav meets the specifications and user needs
- Quality Assurance measure applied to the system design and development, include, but were not limited to:
    - Risk Analysis
    - Product Specifications
    - Design Reviews

8. Clinical Testing

The subject Philips PercuNav System did not require clinical data in order to make a determination for substantial equivalence when compared to the predicate device(s).

9. Conclusion

Based on the conformance to standards, development under Philips Ultrasound's Quality Management System, the successful verification and validation testing, Philips Ultrasound believes that the proposed Philips PercuNav System is substantially equivalent to the predicate devices. Testing performed demonstrated that the proposed PercuNav System with the Tumor Contouring visualization tool meets the defined requirements and performance claims.