

JUN 27 2014

K133901
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Section 2 510(K) Summary

510(k) Summary
Paritic Inc
Traditional 510(k)
pari-path surgical navigation system

Date Prepared:

Dec. 10, 2013

510(k) Applicant:

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Device Information

Trade Name: pari-path surgical navigation system
Common Name: surgical navigation system
Regulation/Classification Name: Computed Tomography X-ray System
Regulation Number: 21 CFR 892.1750,
Regulation Class: II
Classification/Product Code: JAK

Device Description:

The pari-path surgical navigation system is a stereotactic accessory for Computed Tomography(CT) and Ultrasound (US).

It utilizes electromagnetic tracking technology to locate and navigate instruments relative to an image model of the patient anatomy.

It displays the simulated image of an interventional instrument (a tracked insertion tool), such as a biopsy needle, an ablation needle, or probe, on a computer monitor screen that

shows the image model of the patient anatomical target organs and the current and the projected future path of the interventional instrument.

The image model of patient anatomical organs is derived from two-dimensional patient images (scan sets) via the navigation system..

The interventional instrument can be located and navigated on the image model. Ultrasound imaging is incorporated with the system for the situation in which the target organs may move because of patient's respiratory.

The system performs spatial mapping from CT image space to physical space ("registration") to correlate scan sets to the patient.

It consists of a magnetic field transmitter, tracking sensors, system unit, monitor, keyboard, mouse, software, and an "off the shelf" ultrasound device (an optional, not supplied with the system).

Indications for Use:

The pari-path surgical navigation system is a stereotactic accessory for Computed Tomography (CT) and Ultrasound (US).

It displays the simulated image of an interventional instrument (a tracked insertion tool), such as a biopsy needle, an ablation needle, or probe, on a computer monitor screen that shows an image model of the target organs and the current and the projected future path of the interventional instrument. Ultrasound imaging is incorporated with the pari-path surgical navigation system for the situation in which the target organs may move because of patient's respiratory.

It is intended for treatment planning and intra-operative guidance for surgical procedures. It is intended for use in clinical interventions and for anatomical structures where imaging is currently used for visualizing such procedures.

Comparison chart

	Subject Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device
Product Name	Pari-Path surgical navigation system	ig4TM Image Guided System	ABARIS Computer assisted, image-guided surgery system	SonixGPS Needle Sensor	Electro magnetic Tracking System
510(k) Number	K123720	K093146	K053610	K111818	K092619
Manufacture	Paritic Inc	Veran Medical Technologies Inc	Traxtal Technologies Inc	Ultrasonix Medical Corporation	CIVCO Medical Instruments Co.
Intended Use	The Pari-Path surgical navigation system is a stereotactic accessory for Computed Tomography(CT) and Ultrasound (US) . It displays the simulated image of an interventional instrument (a tracked insertion tool), such as a biopsy needle, an ablation	The ig4TM 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	ABARIS is a stereotactic accessory for Computed Tomography(CT), Magnetic Resonance (MR), Ultrasound (US), Positron Emission Tomography (PET), Single Photon Emission Computed Tomography (SPECT), Fluoroscopy, Endoscopy	The device is intended to provide physicians with tools for electro magnetic tracking of instruments with respect to image data. The device is available in two models 0.55mm and 0.9mm in diameter.	The device is intended to provide physicians with tools for electro magnetic tracking of instruments with respect to image data.

	<p>needle, or probe, on a computer monitor screen that shows an image model of the target organs and the current and the projected future path of the interventional instrument. Ultrasound imaging is incorporated with the Pari-path surgical navigation system for the situation in which the target organs may move because of patient's respiratory. It is intended for treatment planning and intra-operative guidance for surgical procedures. It is intended for use in clinical interventions and for</p>	<p>needle on a computer monitor that also displays a CT-based or 3D fluoroscopic x-ray-based model of the target organ(s). The ig4™ System compensates for the patient's respiratory phases. The ig4™ System is intended for use in clinical interventions and for anatomical structures where computed tomography or 3D fluoroscopic x-ray are currently used for visualizing such procedures.</p>	<p>and other imaging systems. It displays the simulated image of a tracked insertion tool such as a biopsy needle, guide wire 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 movements of the patient. This is intended for treatment planning and intra-operative guidance for surgical procedures. The device also supports an image-free mode in</p>		
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	anatomical structures where imaging is currently used for visualizing such procedures.		which the proximity of the interventional device is displayed relative to another device. The device is intended to be used in clinical interventions and for anatomical structures where imaging is currently used for visualizing such procedures. The device is also intended for use in clinical interventions to determine the proximity of one device relative to another.		
Tracking technology	Electro magnetic tracking technology	Same	Same	Same	Same
Instrument images	Displaying dynamically the simulated	Same	Same	Same	N/A

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	images of tracked instruments.				
Patient imaging	Use of acquired patient imaging for anatomy structure	Same	Same	Same	Same
Combining two kind of Images	Combining the simulated images of tracked instruments with the acquired patient imaging.	Same	Same	Same	N/A
Respiratory Concern	Use ultrasound imaging to monitor the real-time target organs' movement caused by patient's respiratory, and display updated spatial positions of the simulated insertion instrument with respect to the ultrasound image in real time.	N/A (ig4™ System does not use ultrasound)	Same (when used in conjunction with an ultrasound system)	Same	N/A

The intended use among new device and predicate devices is same.

- All predicate and new devices have the same intended use for physicians to track and display the simulated instrument with respect to images of the target organs of a patient on a computer monitor screen.
- Like the predicate devices: SonixGPS Needle Sensor (K111818) and ABARIS Computer assisted, image-guided surgery system (K053610), the new subject device, Pari-path surgical navigation system incorporates ultrasound imaging which can observe the movement of anatomy structures caused by the patient's respiration in real time, and displays the spatial position of the simulated instrument on instrument with respect to the ultrasound image in real time.

The new device presents no new issues of safety and effectiveness and the features of intended use are substantially equivalent between the new and predicate devices.

Furthermore, the new device has the same technological characteristics as predicate devices. The new device and predicate devices are substantially equivalent with respect to the design and technology.

The subject device has different software interface than predicate devices. The software interface does not affect performance and functionality. The software interface does not raise different questions of safety and effectiveness than the predicate devices.

The differences for subject device in sensor diameter, length and connection type compared to the predicate devices do not affect performance and functionality. The differences do not raise different questions of safety and effectiveness than the predicate devices.

The device labeling includes an instruction manual which provides technical description, intended use, cautions, warnings, contraindications and instructions to ensure safe and effective use of the device.

Testing and Performance Data:

A set of software and bench testing were performed in order to demonstrate the performance and accuracy of the surgical navigation system and to verify that it does not raise any new safety and effectiveness issues in comparison to its predicate devices.

The testing included the following:

- Electrical safety and electromagnetic compatibility testing according to IEC 60601-1 (and amendments), and IEC 60601-1-2 (and amendment) standards.
- Software verification and validation testing was conducted to evaluate the performance of the surgical navigation and to verify that it performs according to its specifications described in the Software Requirements Specifications (SRS) and Software Design Specifications (SDS).
- Bench test.

Conclusions

The pari-path surgical navigation system has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. Based on the performance testing results, including software validation, bench testing, it has been established that the pari-path system is substantially equivalent to its predicate devices.

Reference:

1. *Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s*, CDHR, ODE August 12, 2005
2. *Guidance for the Content of Premarket Submission for Software Contained in Medical Devices*, CDRH ODE May 11, 2005



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

June 27, 2014

PARITIC INC
KEVIN BARRETT
VICE PRESIDENT
760 PARKSIDE AVENUE
BROOKLYN NY 11226

Re: K133901

Trade/Device Name: Pari-path Surgical Navigation System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: June 15, 2014
Received: June 18, 2014

Dear Mr. Barrett:

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

Janine M. Morris
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)
K133901

Device Name
Pari-path Surgical Navigation System

Indications for Use (Describe)

The pari-path surgical navigation system is a stereotactic accessory for Computed Tomography(CT) and Ultrasound imaging systems.

It displays the simulated image of an interventional instrument (a tracked insertion tool), such as a biopsy needle,an ablation needle ,or probe,on a computer monitor screen that shows an image model of the target organs and the current and the projected future path of the interventional instrument. Ultrasound imaging is incorporated with the pari-path surgical navigation system for the situation in which the target organs may move because of patients's respiratory.

It is intended for treatment planning and intra-operative guidance for surgical procedures. It is intended for use in clinical interventionals and for anatomical structures where imaging is currently used for visualizing such procedures.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)



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