K092564

JUN 17 2010

Attachment E - 510(k) Summary

Date prepared	June 10, 2010
510(k) Owner	Medtronic Navigation, Inc. (Littleton) Phone: 978-698-6045 Fax: 763-367-8304
Contact	Seth Kuzdzal, RA/QA Manager
Trade name	O-Arm Imaging System
Common name	Mobile x-ray system
Classification name	Name: System, X-ray, mobile Regulation: 21 CFR 892.1720 Product code: LHN & OXO
Predicate device	O-arm® Imaging System, which was cleared to market in 510(k)s K050996 and K060344.
Device description	The O-arm® Imaging System is a mobile x-ray system which provides 3D imaging as well as 2D fluoroscopic imaging. The system consists of two parts: the x-ray O-arm® Stand (comprising x-ray generator, flat dynamic x-ray detector, and the x-ray control user interface) and the mobile view station (comprising the image processors, a user interface for image and patient handling, and viewing monitor).
Indications for use	The O-arm® Imaging System is a mobile x-ray system designed for 2D fluoroscopic and 3D imaging and is intended to be used where a physician benefits from 2D and 3D information of anatomic structures and objects with high x-ray attenuation such as bony anatomy and metallic objects. The O-arm® Imaging System is compatible with certain Image Guided Surgery Systems.

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Comparison to the predicate device

	Modified O-arm®	*Predicate O-arm®*
Indications for use	Mobile x-ray imaging designed for 2D fluoroscopic and 3D imaging and is intended to be used where a physician benefits from 2D and 3D information of anatomic structures and objects with high x-ray attenuation such as bony anatomy and metallic objects. Compatible with certain Image Guided Surgery Systems.	The O-Arm™ Imaging System is designed for 2D Fluoroscopic and 3D imaging for intraoperative applications in surgical theaters, particularly for orthopedic applications. The O-Arm™ Imaging System is compatible with certain Image Guided Surgery Systems.
Technology	Same as predicate O-arm®.	Mobile cone-beam x-ray system with isocentric motion options. O-arm® allows 3D image reconstruction from 360° sweep of x-ray source and detector within closed gantry.
Imaging	Same as predicate O-arm® with image quality improvement.	2D Fluoroscopy and 3D Imaging.
Other characteristics	Same as predicate O-arm®.	Sterile accessories, wireless mouse, etc.

Conclusion

Based on design characteristics and imaging performance, the modified O-arm® Imaging System is substantially equivalent to the predicate O-arm® Imaging.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Mr. Seth Kuzdzal
RA/QA Manager
Medtronic Navigation, Inc., Littleton
300 Foster Street
LITTLETON MA 01460

NOV 14 2011

Re: K092564
Trade/Device Name: O-arm® Imaging System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system, mobile
Regulatory Class: II
Product Code: LHN and OXO
Dated: June 10, 2010
Received: June 11, 2010

Dear Mr. Kuzdzal:

This letter corrects our substantially equivalent letter of June 17, 2010.

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 (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 contact 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.

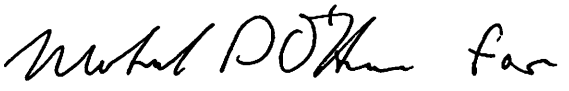
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,



Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K892564

Device Name: O-arm® Imaging System

Indications for Use

The O-arm® Imaging System is a portable x-ray system designed for 2D fluoroscopic and 3D imaging for high contrast objects and anatomic structures.

The O-arm® Imaging System is compatible with certain Image Guided Surgery Systems. The O-arm® Imaging System may be used with medical charged particle radiation therapy systems for verification of correct patient position in relation to isocenter and verification of the treatment fields in relation to anatomical and/or fiducial landmarks.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)