December 22, 2020

medPhoton GmbH
% Daniel Schaffarzick
Quality and Regulatory Affairs Manager
Karolingerstraße 16
Salzburg, Salzburg 5020
AUSTRIA

Re: K203281
Trade/Device Name: Mobile ImagingRing System, IRm, Loop-X Mobile Imaging Robot, Loop-X
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB
Dated: October 30, 2020
Received: November 6, 2020

Dear Daniel Schaffarzick:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K203281

Device Name
Mobile ImagingRing System, IRm
Loop-X Mobile Imaging Robot, Loop-X

Indications for Use *(Describe)*

The IRm is a mobile X-ray system to be used for 2D planar and fluoroscopic and 3D imaging for adult and pediatric patients. It is intended to be used where 2D and 3D information of anatomic structures such as bony anatomy and soft tissue and objects with high X-ray attenuation such as (metallic) implants is required.
The IRm provides an interface that can be used by system integrators for integration of the IRm with image guidance systems such as surgical navigation systems.

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

K203281

In accordance with the requirements of the Safe Medical Device Act, medPhoton GmbH herewith submits a 510(k) Summary.
This 510(k) summary for the Mobile ImagingRing System meets the requirements of 21 CFR 807.92.

Date Prepared: December 22, 2020

Submitter Information:
medPhoton GmbH
Karolingerstraße 16
5020 Salzburg
Austria
Phone: 0043 699 161 053 86
Registration Number: 3012631246
Owner/Operator Number: 10054933

Official Correspondent:
Dr. Daniel Schaffarzick
medPhoton GmbH
Karolingerstraße 16
5020 Salzburg
Austria
Phone: 0043 699 161 054 06

US Agent (Contact):
Michael Friedl
Österr. AußenwirtschaftsCenter New York
120 West 45th Street, 9th Floor
New York, NY 10036
Phone: T +1 212 421 52 50
E-mail: newyork@wko.at

Device(s) Identification:

Device Trade Name(s):	Mobile ImagingRing System, IRm, Loop-X Mobile Imaging Robot, Loop-X
Device common name:	Interventional Fluoroscopic X-Ray System
Device Classification Name:	Interventional Fluoroscopic X-Ray System
Regulation Description:	Image-intensified fluoroscopic x-ray system
Product Code:	OWB
Reference:	per 21 CFR 892.1650
Review Panel:	Radiology
Device Class:	2

Device Description:

The Mobile ImagingRing System (IRm, “Loop-X” or “Loop-X mobile Imaging Robot”) is a robotic, digital X-ray system which supports both 2D planar and fluoroscopic X-ray and 3D Cone-Beam Computed Tomography (CBCT) image acquisition and reconstruction of a patient´s anatomical regions of interest (ROI).

The design of the Mobile ImagingRing is based on a ring-gantry (“ring”) with two arms mounted: the first arm on gantry carries a monoblock X-ray source and a collimator, the second holds a flat-panel detector. The two arms are independently moveable to accommodate individual patient setups and off-center imaging of regions of interest.

The ImagingRing m / Loop-X Imaging Robot is intended for mobile use on patients in general and interventional radiology, in sterile and non-sterile areas. The system can be used for diagnostic and interventional purposes by volumetric or planar X-ray imaging and enables image-guided maneuvers and operations in medical fields such as general surgery, traumatology, orthopedics, neurology or radiotherapy. The system is designed for flexible examinations and treatments with patients lying, sitting or standing, with and without contrast agent. It can also be combined with therapy devices such as linear accelerators, particle beam delivery systems or other irradiation devices with active sources and patient positioning systems in Image Guided Radiation Therapy, Intraoperative Radiation Therapy, Brachytherapy or surgical navigation and assistance systems as well as in combination with surgical robots in Image Guided Surgery, in which the image data provided by the ImagingRing IRm / Loop-X m can be used directly with patient in situ to control the respective therapy maneuvers. Using additional equipment, such as external tracking cameras or the built-in optical cameras, the position of objects such as tracked surgical instruments or pointer tools, for example, can also be determined in the imaging coordinate system. This position data, in combination with the patient's pre- and intra-interventional imaging data, can be used in guided or navigated workflows. The internal cameras of the IRm can also be used to capture pictures and film sequences of the medical procedures.

Intended Use / Indications for Use:

The intended use / indications for use statement has been specified as follows:

> “The IRm is a mobile x-ray system to be used for 2D planar and fluoroscopic and 3D imaging for adult and pediatric patients. It is intended to be used where 2D and 3D information of anatomic structures such as bony anatomy and soft tissue and objects with high X-ray attenuation such as (metallic) implants is required. The IRm provides an interface that can be used by system integrators for integration of the IRm with image guidance systems such as surgical navigation systems.”

The interface between the subject device and other systems is twofold:

- A standard DICOM interface for communication with picture archiving and communication systems (PACS), radiological information systems (RIS) or hospital

information systems (HIS) facilitates import and export of DICOM files from the subject device to an external DICOM server as well as the import of patient data (using DICOM Modality Worklist) from an external DICOM server to the subject device.

- In parallel, a proprietary navigation network-interface for communication of the subject device with external systems (such as surgery planning and support systems or radiation therapy control systems in brachytherapy) is provided. External optical tracking systems can be used to track the position of the IRm's gantry based on passive reflectors (markers) that are attached to it. The IRm's imaging coordinate system can then be registered with an external reference coordinate system and based on this the external system can, for example, visualize tracked surgical instruments on the images provided by the IRm.

Predicate device:

Device Trade Name:	Ziehm Vision RFD 3D
Applicant:	Ziehm Imaging GmbH
510(k) No.:	K142740
Device common name:	Interventional Fluoroscopic X-Ray System
Device Classification Name:	Interventional Fluoroscopic X-Ray System
Regulation Description:	Image-intensified fluoroscopic x-ray system
Classification Product Code:	OWB
Reference:	21CFR892.1650
Review Panel:	Radiology
Device Class:	2

Reference device[1]:

Device Trade Name:	ImagingRing System on Rails
Applicant:	medPhoton GmbH
510(k) No.:	K191267
Device common name:	ImagingRing System on Rails
Device Classification Name:	Accelerator, Linear, Medical
Regulation Description:	Medical charged-particle radiation therapy system
Classification Product Code:	IYE
Reference:	21CFR892.5050
Review Panel:	Radiology
Device Class:	2

The Mobile ImagingRing System is considered substantial equivalent to the Ziehm Vision RFD 3D (K142740).

1. Intended use, medical application and treatment method as well as the basic parameter settings are equivalent for the Mobile ImagingRing System and the predicate device.
2. There is no significant difference in intended use or technology.

[1] As proposed in the FDA guidance “The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]” (December 27, 2011), a reference device is used to support the scientific methods used to evaluate the different technological characteristics’ effect on safety and effectiveness.

Summary of Technological Characteristics:

Characteristics	Ziehm Vision RFD 3D (predicate device)	Mobile ImagingRing System (IRm or "Loop-X mobile imaging robot") (subject device)
General		
510(k)	K142740	(K-number not yet assigned)
Manufacturer	Ziehm Imaging GmbH	medPhoton GmbH
Product code	OWB	OWB
Intended Use / Indications for Use	The Ziehm Vision RFD 3D system is intended for use in providing both 2D and 3D medical imaging for all adult and pediatric populations, using pulsed and continuous fluoroscopic imaging. The device provides 2D medical imaging for fluoroscopy, digital subtraction, and acquisition of cine loops during diagnostic interventional and surgical procedures where intra-operative imaging and visualization of complex anatomical structures of both lower and higher contrast density are required. Such procedures may include but are not limited to those of interventional cardiology, heart surgery, hybrid procedures, interventional radiology, interventional angiography, electrophysiology, pediatrics, endoscopic, urological, gastroenterology, orthopedic, maxillofacial surgery, neurology, neurosurgery, critical care, emergency room procedures, and those procedures visualizing structures of the cervical, thoracic, and lumbar regions of the spine and joint fractures of the upper and lower extremities, and where digital image data is required for Computer-Assisted Surgery procedures. The device is also intended to provide 3D medical imaging of patients during orthopedic,	The IRm is a mobile x-ray system to be used for 2D planar and fluoroscopic and 3D imaging for adult and pediatric patients. It is intended to be used where 2D and 3D information of anatomic structures such as bony anatomy and soft tissue and objects with high X-ray attenuation such as (metallic) implants is required. The IRm provides an interface that can be used by system integrators for integration of the IRm with image guidance systems such as surgical navigation systems..

	neurological, intra-operative surgical procedures and where the clinician benefits from 3D visualization of complex anatomical structures, such as but not limited to those of high contrast objects, bones, joints, maxillofacial, cervical, thoracic, and lumbar regions of the spine, pelvis, acetabulum and joint fractures of the upper and lower extremities, and where digital image and C-arm positioning data is required for Computer-Assisted Surgery procedures. The visualization of such anatomical structures assists the clinician in the clinical outcome. At the discretion of a physician, the device may be used for other imaging applications. This device does not support direct radiographic film exposures and is not intended for use in performing mammography. The system is not intended for use near MRI systems.	
System Design	C-arm	Gantry
Imaging Modes		
Isocentric imaging	✓	✓
Non-isocentric imaging	✓	✓
2D planar imaging mode	✓	✓
2D Fluoroscopic imaging mode	✓ (pulsed and continuous)	✓ (pulsed and continuous)
3D imaging mode	✓	✓
CBCT	✓	✓
X-ray System		
Power Rating [kW@100kVp]	max. 25	max. 15
Voltage Range [kV]	40-120	40-120
Current Range [mA]	0.2-250	5-80
Pulse length [ms]	4-40	2-35
Tube Type	Rotating anode	Rotating anode
Anode Material	Tungsten rhenium molybdenum	Tungsten rhenium molybdenum
Fixed Filtration	≥ 4.3 mm Al eq.	4.4 mm Al eq.
Image Detector		

Detector Technology	Amorphous silicon flat panel detector (aSi)	Amorphous silicon flat panel detector (aSi)
Panel Size [cm²]	30 x 30	43.2 x 43.2
Max. detector resolution [pixels]	1536 x 1536	2880 x 2880
User Interface		
Remote Control Panels (incl. radiation buttons, radiation warning lamps and emergency stop buttons)	✓	✓
Wired footswitch	✓	✓
Other Components		
Anti-Scatter Grids	✓	✓
Beam Limiter / Collimator	✓	✓
Lasers	✓ (class 2M)	✓ (class 1)
Monitor(s)	✓	--
Collision protection	✓	✓
Electrical requirements		
Input specification	100-240 VAC (± 10%), 50/60 Hz	120-230 VAC (± 10%), 50/60 Hz
Environmental Conditions		
Operation		
Temperature [°C]	10 – 35	15 – 32
Humidity [%] (non-condensing)	20 – 70	30 – 60
Atmospheric Pressure [mbar]	790 – 1060	800 – 1100
Storage		
Temperature [°C]	-5 – 55	0 – 40
Humidity [%] (non-condensing)	20 – 70	10 – 75
Atmospheric Pressure [mbar]	790 – 1060	750 – 1100
Transport		
Temperature [°C]	-5 – 55	-10 – 50
Humidity [%] (non-condensing)	20 – 70	5 – 75
Atmospheric Pressure [mbar]	790 – 1060	750 – 1100
Other system specifications		
Opposing source detector distance (SDD) [cm]	104.5	126
Max. rotational speed [°/s]	15	16 (7 for certain IGRT applications)

Table 1: Comparison of technological characteristics of IRS and the predicate XVI R5.0

Like the listed predicate device, the medPhoton Mobile ImagingRing System (IRm) is a mobile x-ray system intended to be used for 2D fluoroscopic and 3D imaging (adult and pediatric patients). Both devices are intended to be used where 2D and 3D information of anatomic structures such as bony anatomy and objects with high X-ray attenuation such as (metallic) implants is required. Also, both devices are prepared for (equipped with respective interfaces) integration with image guidance systems, such as surgical navigation systems.
The technological characteristics (materials, energy sources, other features) of the subject device are not significantly different – i.e. can be considered the same – as those of the predicate device.
The device design of the subject device and the predicate device (gantry vs. C-arm) is significantly different, however, this difference raises no new questions of safety and effectiveness. The existing questions of safety and effectiveness have been addressed and answered in the submission of the reference device (K191267) which has the same design as the subject device. The Mobile ImagingRing System does not introduce new potential hazards or safety risks.
Since the subject device can therefore be considered to be as safe and effective as the predicate device and since they also have the same intended use, medPhoton is certain that the devices are substantially equivalent.

Summary of performance testing:

Bench Testing:
Non-clinical bench performance testing has been conducted to further support substantial equivalence of the subject device and the predicate device. The main aspects in determining substantial equivalence are the intended use of the devices, their technological characteristics as well as safety and effectiveness of the devices.

A system level validation has been conducted, which provides evidence that the Mobile ImagingRing System (IRm, Loop-X Mobile Imaging Robot, Loop-X) meets all customer and system requirements and is able to perform according to its intended use.

Clinical use of the device in general and its clinical imaging performance in particular have been tested using phantoms and cadavers. Those clinical imaging tests were conducted with the subject device as well as the predicate device. Results suggest that the subject device performs at least as good as the predicate device (in terms of resolution capabilities) or better (in terms of a larger dynamic range) and therefore support the demonstration of substantial equivalence.

Although safety and effectiveness of the subject device's design have been demonstrated for a

reference device (with the same design), additional bench testing pertaining to a variety of different mechanical characteristics of the device design were conducted. Results demonstrate the safety and effectiveness of the subject device in terms of its design.

Voluntary consensus standards applied during design and development include but are not limited to IEC 60601-1, IEC 60601-1-2, IEC 60601-1-3, IEC 60601-2-43, IEC 60601-2-54, IEC 62304, IEC 62366 and ISO 14971. Standard compliance has been demonstrated in a variety of tests conducted internally (by medPhoton) and by an external accredited testing laboratory.

In summary, the results of all non-clinical bench performance tests support substantial equivalence of the subject device and the predicate device and demonstrate safety and effectiveness of the subject device.

Animal Testing:
medPhoton GmbH did not perform any animal testing for the Mobile ImagingRing System.

Clinical Testing:
medPhoton GmbH did not perform any clinical testing for the Mobile ImagingRing System.

Conclusion: medPhoton GmbH believes that the Mobile ImagingRing System is substantially equivalent to the currently legally marketed devices. The Mobile ImagingRing System does not introduce new indications for use, has the same technological characteristics and does not introduce new potential hazards or safety risks.