March 28, 2025

medPhoton GmbH
℅ Thomas Fessmann
Quality Management and Regulatory Affairs
Karolingerstraße. 16
Salzburg, Salzburg 5020
AUSTRIA

Re: K234067
Trade/Device Name: ImagingRing m (Version 2.0);
Loop-X (Version 2.0);
Loop-X Mobile Imaging Robot (Version 2.0)
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB
Dated: February 26, 2025
Received: February 26, 2025

Dear Thomas Fessmann:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

Lu Jiang, Ph.D.
Assistant Director
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DHT8B: Division of Radiological Imaging
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K234067

Device Name

ImagingRing m (Version 2.0);
Loop-X (Version 2.0);
Loop-X Mobile Imaging Robot (Version 2.0)

Indications for Use *(Describe)*

The ImagingRing m 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 ImagingRing m provides an interface that can be used by system integrators for integration of the ImagingRing m 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.

510(k) #: K234067

510(k) Summary

Prepared on: 2025-03-28

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	medPhoton GmbH
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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	ImagingRing m (Version 2.0); Loop-X (Version 2.0); Loop-X Mobile Imaging Robot (Version 2.0)
Common Name	Interventional Fluoroscopic X-Ray System
Classification Name	Image-intensified Fluoroscopic X-Ray System
Regulation Number	892.1650
Product Code	OWB

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K203281	ImagingRing m	OWB

Device Description Summary

21 CFR 807.92(a)(4)

The ImagingRing m (Version 2.0) is from a technical point of view the same system as its already approved predecessor ImagingRing m (K203281). The only difference is the implementation of a new x-ray source in combination with a software upgrade, which allows for higher power settings. The ImagingRing m functions as 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 ImagingRing m (Version 2.0) provides an interface that can be used by system integrators for integration of the ImagingRing m (Version 2.0) with image guidance systems such as surgical navigation systems.

The ImagingRing m (Version 2.0) consists of the ring gantry and respective arms carrying the X-Ray source and detector and directly

integrates all necessary electronic and computer components along with low-level software to realize coordinated motion and X-ray emission in the device's ring carrier and legs. The IImagingRing m (Version 2.0) device also provides a detachable Remote Control Panel (RCP) component that provides a display and controls elements such that users can interact with the machine.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The ImagingRing m 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 ImagingRing m provides an interface that can be used by system integrators for integration of the ImagingRing m with image guidance systems such as surgical navigation systems.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use are the same.

Technological Comparison

21 CFR 807.92(a)(6)

The device has the same technological characteristics as its predecessor device. The difference is that a new x-ray source is used in combination with a software upgrade to achieve higher power settings. The predecessor's available energy is 40-120 kV and the new device's (Version 2.0) available energy is 40-140 kV with the new x-ray source and software upgrade. Alongside the software upgrade new features were introduced to the 2.0 device, such as the infrared guided motion compensation and 3D extended field of view (Multi-slit / Multi-slice) imaging.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Summary of Non-Clinical and Clinical Testing Supporting Substantial Equivalence
As part of the comprehensive non-clinical and clinical testing conducted to evaluate the subject device and its new features, multiple studies have been carried out in collaboration with renowned institutions. These investigations encompass a variety of testing environments, including cadaver studies (e.g. at Highridge Cadaver Lab in the US, Paracelsus Medical University in Austria) and clinical evaluations at reference customer sites, to ensure a thorough assessment of the device's performance, safety, and usability.

Overview of Testing Approach
The testing framework incorporated both non-clinical and clinical methodologies to provide a robust foundation for determining substantial equivalence. Non-clinical testing included cadaver studies performed at multiple institutions, aiming to simulate real-world conditions while maintaining control over experimental variables. Clinical studies involved patient imaging under standard operating conditions to validate the new features' impact in routine diagnostic settings.

Key Investigations and Findings
One of the primary objectives was to analyze whether the introduction of a higher X-ray energy option (140 kVp) affects diagnostic accuracy and usability. Cadaver studies compared 3D CBCT images acquired at 120 kVp and 140 kVp, demonstrating that the increased tube voltage does not negatively impact image quality. Instead, higher penetration power is beneficial, particularly for larger patients or cases involving metallic implants.
The implementation of infrared-based motion compensation was assessed through both cadaver and clinical studies, evaluating its effectiveness in reducing motion-related artifacts. By acquiring and reconstructing images with and without motion compensation, it was confirmed that this feature improves image quality without altering total radiation dose. This finding is particularly relevant in cases where respiratory motion or involuntary patient movement could otherwise degrade image clarity.
The introduction of extended Field of View (FOV) techniques, including longitudinally extended 3D imaging and 2D topogram scanning, was also rigorously evaluated. These features allow for better anatomical coverage, facilitating more precise planning of subsequent CBCT scans. Through a combination of clinical and cadaver studies, it was demonstrated that extended FOV scanning enhances workflow efficiency while maintaining high image quality and adhering to radiation dose optimization principles.

The following FDA Guidances have been used:
1. Content of Premarket Submissions for Device Software Functions Guidance for Industry and Food and Drug Administration Staff June 2023 - used for the preparation of this 5 10k submission.
2. Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions Guidance for Industry and Food and Drug Administration Staff September 2023.
3. Pediatric Information for X-ray Imaging Device Premarket Notifications Guidance for Industry and Food and Drug Administration Staff November 2017.

Standards Used in the development and testing:
IEC 62304:2015
IEC 60601-1:2005 + A1:2012
IEC 60601-1-2:2014
IEC 60601-1-3:2008 + A1:2013
IEC 60601-1-6:2010 + A1:2013
IEC 60601-2-28:2017
IEC 60601-2-43:2010/AMD1:2017
IEC 60601-2-54:2009/AMD2:2018

Conclusion:
Across all evaluated features, clinical and non-clinical testing confirmed that the modifications introduced in the subject device do not negatively impact its clinical performance. Instead, enhancements such as higher X-ray energy, motion compensation, and extended FOV capabilities provide tangible benefits in patient imaging. In summary, these non-clinical and clinical imaging studies, through the comparison of image quality, artifacts, anatomical representation, and dose, demonstrate the substantial equivalence of the devices with the tested new features to their respective base versions or similar devices.