iCat Solutions Ltd
% Bhoomika Joyappa
Senior Regulatory Consultant
Medical Device Academy, Inc.
345 Lincoln Hill Rd
Shrewsbury, Vermont 05738

April 8, 2025

Re: K242552
Trade/Device Name: Horos Mobile
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: March 11, 2025
Received: March 12, 2025

Dear Bhoomika Joyappa:

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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242552

Device Name

Horos Mobile

Indications for Use *(Describe)*

Horos Mobile is a software device intended for viewing images acquired from computed tomography (CT), computed radiography (CR), magnetic resonance (MR), ultrasound (US) and other DICOM compliant medical imaging systems when installed on suitable commercial standard hardware.
Images and data can be stored, communicated, processed, and displayed within the system.
It is intended for use as a diagnostic and review tool by trained healthcare professionals.
This device is not intended to replace full workstations and should be used only when there is no access to a workstation.
This device is not to be used for mammography.
It is the User's responsibility to operate the device in accordance with the software and hardware requirements listed in the instructions for use, in particular ensuring that display quality, ambient light conditions, and image compression ratios are consistent with the clinical application.

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) Summary

K242552

1. SUBMITTER

Company Name	iCat Solutions Ltd
Address	51-59 Rose Lane, NR1 1BY, Norwich, United Kingdom
tel	+44(0)7517456306
email	gm@icat.solutions
Contact Person	Georgios Michalopoulos

2. DATE PREPARED

18-JUL-2024

3. DEVICE

Device Trade Name	Horos Mobile
Classification Name	Medical Image Management and Processing System
Regulation	21 CFR 892.2050
Regulatory Class	Class II
Device Panel	Radiology
Product Classification Code	LLZ

4. PREDICATE DEVICES

Predicate Device

Predicate Device Manufacturer	iCat Solutions Ltd
Predicate Device Name	Horos MD™ (K232589)
Predicate Device 510(k)	K232589

Reference Device

Reference Device Manufacturer	MIM SOFTWARE INC.
Reference Device Trade Name	Mobile MIM (K112930)
Reference Device 510(k)	K112930

5. DEVICE DESCRIPTION

The Horos Mobile is an interactive medical image display software device for diagnostic image viewing of radiological images for the following modalities: X-ray, CT, MRI, Ultrasound, and XA for iOS and iPadOS platforms. The technological characteristics and the indications of use are identical to those of the Horos MD™ (K232589). The subject device provides both 2D and 3D image visualization tools for CT and MRI scans from various makes and models of image acquisition hardware. It does not produce any original medical images and does not contain controls for the direct operation of a diagnostic imaging system.
Horos Mobile conforms to the DICOM standard to allow the sharing of medical images with other digital imaging systems such as PACS (Picture Archiving and Communication System).
The Horos Mobile software device runs on the iOS and iPadOS platforms, leveraging of their optimized 3D graphic capabilities, which are provided by the METAL framework developed and maintained by Apple Inc.
The user interface of the software follows Apple's Human Interface Guidelines (HIG) to create a user interface that is intuitive and easy to use for users who are familiar with other Apple products. Typical users of this device are radiologists and clinicians who are familiar with 2D scan images.
Horos Mobile operates on "off-the-shelf 'portable hardware devices and is therefore subject to factors not typical for reading room workstations (e.g. screen size, environmental variability, network dependencies, etc.). It is therefore required that the user follows the operating instructions properly and utilizes the risk mitigation features in order to make decisions safely and effectively.

6. INDICATIONS FOR USE

Horos Mobile is a software device intended for viewing images acquired from computed tomography (CT), computed radiography (CR), magnetic resonance (MR), ultrasound (US) and other DICOM compliant medical imaging systems when installed on suitable commercial standard hardware. Images and data can be stored, communicated, processed, and displayed within the system.
It is intended for use as a diagnostic and review tool by trained healthcare professionals.
This device is not intended to replace full workstations and should be used only when there is no access to a workstation.
This device is not to be used for mammography.
It is the User's responsibility to operate the device in accordance with the software and hardware requirements listed in the instructions for use, in particular ensuring that display quality, ambient light conditions, and image compression ratios are consistent with the clinical application.

7. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The following characteristics were compared between the subject device and the predicate device in order to demonstrate substantial equivalence:

Table 1: Comparison of Horos Mobile with Horos MD™ (K232589) and Mobile MIM (K112930)

Characteristics	Subject device Horos Mobile	Primary Predicate Horos MD™	Reference Device Mobile MIM	Justification for differences with predicate device
Manufacturer	iCat Solutions Ltd	iCat Solutions Ltd	MIM SOFTWARE INC.	-
510(k) Number	TBD	K232589	K112930	-
Product classification	Class II	Class II	Class II	Same
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	21 CFR 892.2050	Same
Product code	LLZ	LLZ	LLZ	Same
Type of use	Prescription (Rx Only)	Prescription (Rx Only)	Prescription (Rx Only)	Same
Class	II	II	II	Same
Regulations number	21 CFR 892.2050	21 CFR 892.2050	21 CFR 892.2050	Same
Regulation Name^	Medical Image Management and Processing System	Medical Image Management and Processing System	Picture archiving and communications system	Same (For Reference Device: 21 CFR 892.2050 name has been amended in April 2021)
Classification Name	System, image processing, radiological	System, image processing, radiological	System, image processing, radiological	Same
Product code	LLZ	LLZ	LLZ	Same

Indications for Use	Horos Mobile is a software device intended for viewing images acquired from computed tomography (CT), computed radiography (CR), magnetic resonance (MR), ultrasound (US) and other DICOM compliant medical imaging systems when installed on suitable commercial standard hardware. Images and data can be stored, communicated, processed, and displayed within the system. It is intended for use as a diagnostic and review tool by trained healthcare professionals. This device is not intended to replace full workstations and should be used only when there is no access to a workstation. This device is not to be used for mammography. It is the User's responsibility to operate the device in accordance with the software and hardware requirements listed in the instructions for use, in particular ensuring that display quality, ambient light	Horos MD™ is a software device intended for viewing images acquired from computed tomography (CT), computed radiography (CR), magnetic resonance (MR), ultrasound (US) and other DICOM compliant medical imaging systems when installed on suitable commercial standard hardware. Images and data can be stored, communicated, processed, and displayed within the system. It is intended for use as a diagnostic and review tool by trained healthcare professionals. This device is not to be used for mammography. It is the User's responsibility to operate the device in accordance with the software and hardware requirements listed in the instructions for use, in particular ensuring that monitor (display) quality, ambient light conditions, and image compression ratios are consistent with the clinical application.	The Mobile MIM software program is used for the viewing, registration, fusion, and/or display for diagnosis of medical images from the following modalities: SPECT, PET, CT, MRI, X-ray and Ultrasound. Mobile MIM can be used to review images, contours, DVH, and isodose curves from radiation treatment plans. Mobile MIM can be used to approve these plans. Mobile MIM provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation. This device is not to be used for mammography.	The primary indication of the subject device and the predicate device is to view medical images from different modalities for diagnosis. This subject device is not intended to replace a full workstation and should be used only where there is no access to a workstation. This operational limitation is consistent with the indications for use of the referenced device.

	conditions, and image compression ratios are consistent with the clinical application.			
Users	Trained healthcare professionals such as radiologists, clinicians and other qualified physicians	Trained healthcare professionals such as radiologists, clinicians and other qualified physicians	Trained healthcare professionals	Same
Mammography diagnostic use	No	No	No	Same

Imaging modalities	• CT • MR • CR • DR • US	• CT • MR • CR • DR • US	• SPECT • PET • CT • MR • X-ray • Ultrasound	Same as the primary predicate device
Communications	DICOM	DICOM	DICOM	Same
Installation	Apple Handheld Devices	Local computers (Apple)	Apple Handheld Devices (Apple)	Difference: The subject device is compatible with iOS/iPadOS hardware, while the predicate device is compatible with MacOS hardware. The subject device has been adequately tested, and the difference does not raise concerns regarding safety or performance. Same as the reference device, the subject device can display images from various modalities on iOS and iPadOS hardware.

				Hence, both the subject and the reference devices are considered substantially equivalent concerning the aspects of hardware for diagnostic image viewing.
Operating system for diagnostic viewing	iOS (iPhone), iPadOS (iPad)	MacOS (Mac)	iOS (iPhone, iPod Touch), iPadOS (iPad)	Difference: The subject device is compatible with iOS/iPadOS, while the predicate device is compatible with MacOS. The subject device has been adequately tested, and the difference does not raise concerns

				regarding safety or performance. Same as the reference device, the subject device can display images from various modalities on iOS and iPadOS. Hence, both the subject and the reference devices are considered substantially equivalent concerning the aspects of the operating system for diagnostic image viewing.
User authentication (unique login)	Yes	Yes	Yes	Same
Receive, Store, Retrieve, Display, and Process Digital Medical Images	yes	yes	yes	Same

Basic visualization tools	• Grayscale display • Rotate • Pan • Zoom • Fit to screen • Scroll • Flip horizontal / vertical • Axial / coronal / sagittal views • Cross-hair • Adjustable windowing (WW/WL) • HU (Hounsfield Unit) • Slice indicator • Reset	• Grayscale display • Rotate • Pan • Zoom • Fit to screen • Scroll • Flip horizontal / vertical • Axial / coronal / sagittal views • Cross-hair • Adjustable windowing (WW/WL) • HU (Hounsfield Unit) • Slice indicator • Reset	• Grayscale display • Pan • Zoom • Scroll • Axial / coronal / sagittal views • Cross-hair • Adjustable windowing (WW/WL) • HU (Hounsfield Unit) • Slice indicator	Same as the primary predicate device. The subject device includes additional image manipulation features compared to the reference device. These features use the exact same technology as the primary predicate device. The additional visualization tools compared to the reference device, do not alter the device's intended use or indications for use, nor they introduce any new safety risks. Therefore, there is no risk to the device's safety or performance.

Advanced tools	• Volume Rendering (3D) • MPR	• Volume Rendering (3D) • MPR	• MPR	Same as the primary predicate device
Measurements	• Line • Angle • Area (circular, irregular shape, polygonal) • Point • Cobb Angle • CTR	• Line • Angle • Area (circular, irregular shape, polygonal) • Point • Cobb Angle • CTR	• Line (Distance) • Area - Circular (SUV)	Same as the primary predicate device. The additional measurement tools compared to the reference device, do not alter the device's intended use or indications for use, nor they introduce any new safety risks. Therefore, there is no risk to the device's safety or performance.
Annotations	yes	yes	yes	Same

Anonymization function	yes	yes	no	Same as the primary predicate device.The reference device does not include Anonymization feature. This addition does not alter the device's intended use or indications for use, nor does it introduce any new safety risks. Therefore, there is no risk to the device's safety or performance.
Studies comparison	yes	yes	no	Same as the primary predicate device
Share function	yes	yes	yes	Same
Export functions	Yes (JPEG, .dcm, .zip)	Yes (JPEG, .dcm, .zip)	Yes (.mma)	Same as the primary predicate device
Report generation	No	No	No	Same

Device type/ form	Software device that operates on off-the-shelf hardware	Software device that operates on off-the-shelf hardware	Software device that operates on off-the-shelf hardware	Same
Non-Clinical Performance testing		Non-Clinical Performance testing		
DICOM standard for data exchange	NEMA PS3.1 2023b (2023) Digital Imaging and Communications In Medicine (Dicom) Set	NEMA PS3.1 2023b (2023) Digital Imaging and Communications In Medicine (Dicom) Set	Not Available	Same
JPEG standard for image compression	IEC/ ISO 10918-1, Edition 1 (1994-02-15), Information Technology – Digital Compression and Coding of Continuous-Tone Still Images: Requirements And Guidelines [Including: Technical Corrigendum 1 (2005)	IEC/ ISO 10918-1, Edition 1 (1994-02-15), Information Technology – Digital Compression and Coding of Continuous-Tone Still Images: Requirements And Guidelines [Including: Technical Corrigendum 1 (2005)	Not Available	Same

^The Regulation 21 CFR 892.2050 name has been amended in April 2021

8. EVALUATION OF SIMILARITIES AND DIFFERENCES

The Horos Mobile demonstrates substantial equivalence to the primary predicate, Horos MD™ (K232589) , and reference device, Mobile MIM (K112930) by MIM SOFTWARE INC., in terms of classification, regulation, and intended medical image management use.

There is no difference between the subject device (Horos Mobile) and the predicate and reference devices in terms of its intended use, indications for use, and fundamental scientific technology. The subject device has equivalent intended use and indications for use as the predicate device, with a minor difference in terms of OS compatibility. This minor difference in OS compatibility does not raise any new concerns regarding safety or effectiveness.

The subject device is equivalent in terms of technological characteristics, including overall design, mechanism of action, mode of operation, and performance characteristics, as well as its intended use, to the primary predicate device. The non-clinical performance test data, as well as the software verification and validation, demonstrate that the subject device performs comparably to, and is as safe and effective as, the predicate device.

To address additional indications, MIM has been selected as the reference device, which supports portable device characteristics and accessibility when a full workstation is not available. Thus, Horos MD™ (K232589) is substantially equivalent to both the predicate and reference devices in terms of safety and effectiveness. In accordance with 21 CFR Part 807 and based on the information provided in this premarket notification, Horos MD™ (K232589) is substantially equivalent to the predicate device.

9. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Non-Clinical Data

- **Software Verification and Validation Testing**

All of the different components of Horos Mobile software have been tested to ensure that the system as a whole provides all the capabilities necessary to operate according to its intended use. Software verification and validation testing were conducted, and documentation was provided as detailed in FDA's Guidance for Industry and FDA Staff: "Guidance for the content of Premarket Submissions for Software Contained in Medical Devices."
iCat Solutions Ltd has implemented security features for the device and data protection. Cybersecurity requirements, risk analysis, and mitigation was addressed in accordance with FDA guidance *Content of Premarket Submission for Management of Cybersecurity in Medical Devices* (Oct 2014).

- **Bench Performance Testing**

No clinical testing was required to demonstrate safety or effectiveness for the subject device as the device's non-clinical (bench) testing was sufficient to support the intended use of the device.
The measurement accuracy for the distance (length), angle, point, and area features was validated using automated tests with Digital Reference Objects (DROs) compared against known values. The DROs (n=75 test cases) created were representative of the clinical range typically encountered in radiology practice (1-190 mm). Inter-system error (robustness) and intra-system error (consistency) were assessed using automated processes.

Function	Accuracy
Distance (1-10mm)	100%
Distance (>10mm)	100%
Area (1-10mm)	100%
Area (>10mm)	100%
Angle (1-190mm)	100%
Point (1-190mm)	100%

Display Performance Bench Testing Summary

Bench testing was conducted to evaluate the display performance of the Horos Mobile DICOM Viewer on the iPhone 14 Pro Max and the iPad Pro 12.9-inch. This testing, carried out in accordance with IEC 62563-1, assessed the following key performance characteristics:

- **Luminance Response Evaluation (DICOM GSDF)**
- **Luminance Uniformity Evaluation**
- **Qualitative Image Quality Evaluation**, including:
    - Greyscale evaluation
    - Greyscale (contrast) resolution evaluation
    - Contrast evaluation
    - Pixel resolution evaluation
    - Angular viewing evaluation

This bench testing demonstrated that the designated hardware platforms are appropriate for Horos Mobile's intended use and support substantial equivalence of the Horos Mobile to the predicate devices.

10. CONCLUSIONS

There is no difference between the subject device (Horos Mobile) and the predicate and reference devices in terms of its intended use, indications for use and fundamental scientific technology. Neither device differs in usage, safety, or effectiveness, thus no new questions regarding safety or effectiveness are raised. The non-clinical performance test data and software verification and validation demonstrate that the subject device performs comparably to and is as safe and effective as the predicate device. In accordance with the 21 CFR Part 807 and based on the information provided in this premarket notification, Horos Mobile is substantially equivalent to the predicate device.