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

January 3, 2024

Re: K232589
Trade/Device Name: Horos MD™
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: December 13, 2023
Received: December 13, 2023

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.

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

Jessica Lamb
Assistant Director
DHT8B: Division of Radiologic 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K232589

Device Name

Horos MD™

Indications for Use *(Describe)*

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.

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.

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510(k) Summary		
Horos MD (HOROSMD)	**Document:** DOC-21	**Date:** 2023/08/25 14:27:46

1. Description

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

2. SUBMITTER

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

3. Date Prepared

2023/07/21

4. DEVICE

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

5. PREDICATE DEVICE

Predicate Manufacturer	Pixmeo, Sarl
Predicate Trade Name	Osirix MD™
Predicate 510(k)	K101342

No reference devices were used in this submission.

6. DEVICE DESCRIPTION

The Horos MD™ is an interactive image display and navigation software device for diagnosis of medical images. It provides both 2D and 3D image visualization tools for CT and MRI scans from different 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 MD™ 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 MD™ software device runs on the macOS X platform, taking advantage of its 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) in order 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.

7. INDICATIONS FOR USE

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.

8. 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 MD™ with Osirix MD™ (K101342).

Characteristics	Subject device Horos MD™	Primary Predicate Osirix MD™	Justification for differences
Submitter	iCat Solutions Ltd	Pixmeo, Sarl	-
510(k) Number	K232589	K101342	-
Product classification	Class II	Class II	
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	Same
Product code	LLZ	LLZ	Same
Type of use	Prescription (RX Only)	Prescription (RX Only)	Same
Class	II	II	
Regulations number	21 CFR 892.2050	21 CFR 892.2050	
Regulation Name^	Medical Image Management and Processing System	Picture archiving and communications system	21 CFR 892.2050 name has been amended in April 2021
Classification Name	System, image processing, radiological	System, image processing, radiological	Same
Product code	LLZ	LLZ	Same
Indications for Use	Horos MD™ is a software device intended for viewing images acquired	OsiriX MD"M isa software device intended for viewing of images	Same.

	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.	acquired from CT, MR, CR, DR, US and other DICOM compliant medical imaging systems when installed on suitable commercial standard hardware. Images and data can be captured, stored, communicated, processed, and displayed within the system and or across computer networks at distributed locations. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary diagnosis or image interpretation. For primary diagnosis, post process DICOM "for presentation" images must be used. Mammographic images should only be viewed with a monitor approved by FDA for viewing mammographic images. It is the User's responsibility to ensure monitor quality, ambient light conditions, and image compression ratios are consistent with the clinical application.	The subject device is contraindicated for Mammography. Therefore, the subject device eliminates the risks associated with the analysis of mammographic images.
Users	Trained healthcare professionals such as radiologists, clinicians and other qualified physicians	Trained healthcare professionals	Same
Mammography diagnostic use	No	Yes (Mammographic images should only be viewed with a monitor approved by FDA for viewing mammographic images)	The subject device is contraindicated for Mammography. Therefore, the

			subject device eliminates the risks associated with the diagnosis and analysis of mammographic images.
Imaging modalities	• CT • MR • CR • DR • US	• CT • MR • CR • DR • US	Same
Communications	DICOM	DICOM	Same
Installation	Local computers	Local computers	Same
Operating system for diagnostic viewing	MacOS (Mac)	MacOS (Mac)	Same
User authentication (unique login)	Yes	Yes	Same
Access to DICOM studies	• Connect to existing onsite or remote PACS • Local computer/server • USB drives / CD / DVD	• Connect to existing onsite or remote PACS • Local computer/server • USB drives / CD / DVD	Same
Basic visualization tools	• Grayscale display • Rotate • Pan • Zoom • Magnification • Fit to screen. • Scroll • Flip horizontal / vertical • Axial / coronal / sagittal views • Cross-hair	• Grayscale display • Rotate • Pan • Zoom • Magnification • Fit to screen • Scroll • Flip horizontal / vertical • Axial / coronal / sagittal views • Cross-hair	Same

	• Adjustable windowing (WW/WL) • HU (Hounsfield Unit) • Slice indicator • Reset	• Adjustable windowing (WW/WL) • HU (Hounsfield Unit) • Slice indicator • Reset	
Advanced tools	• Volume Rendering (3D) • MPR	• Volume Rendering (3D) • MPR • SSD	The subject device does not include SSD. This limitation 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.
Measurements	• Line • Angle • Area (circular, irregular shape, polygonal) • Point • Cobb Angle • CTR	• Line • Angle • Area (circular, irregular shape, polygonal) • Point	The subject device has additional measuring functions. Subject device features and functions are described in the user's manual and tested with intended users for clinical use. Additional measurement functions do not change the device's intended use or

			indications for use. The differences do not raise any new safety risks, so there is no risk to the device's safety or performance.
Annotations	yes	yes	Same
Anonymization function	yes	yes	Same
Studies comparison	yes	yes	Same
Share function	yes	yes	Same
Export functions	Yes (JPEG, .dcm, .zip)	Yes (JPEG, PNG,.dcm, .zip)	The subject device exports files in JPEG, .dcm, and .zip formats but not in PNG format. This limitation 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.
Report generation	No	No	Same
Device type/ form	Software device that operates on off-the-shelf hardware	Software device that operates on off-the-shelf hardware	Same
Non-Clinical Performance testing			

DICOM standard for data exchange	NEMA PS3.1 2023b (2023) Digital Imaging and Communications In Medicine (Dicom) Set	NEMA PS 3.1 - 3.20 (2016) Digital Imaging and Communications In Medicine (Dicom) Set	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)	Same

9. EVALUATION OF SIMILARITIES AND DIFFERENCES

The main differences between the subject device and the primary predicate is in the system installation (installation via the Apple AppStore versus installation from a .dmg binary file for the predicate device) and the support of mammography images (Horos MD™ must not be used for mammography diagnostic use)
Horos MD™ and the primary predicate device have the same technical characteristics, general function, application, intended use, and does not raise any new potential safety risks and is equivalent in performance. In terms of use and functions, both systems access, upload, and display DICOM images and metadata, and provide tools and resources to trained healthcare professionals for study review and analysis.

10. 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 MD™ 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 Digital Reference Objects compared against the known values. The Digital Reference Objects (n=75 test cases) created were representative of the clinical range typically encountered in radiology practice (1-190 mm). Inter-operator error (reproducibility), and intra-operator error (repeatability) were assessed.

Function	Accuracy
Distance (1-10mm)	99.68%
Distance (>10mm)	99.82%
Area (1-10mm)	99.19%
Area (>10mm)	99.66%
Angle (1-190mm)	100%
Point (1-190mm)	100%

11. CONCLUSIONS

There is no difference between the subject device (Horos MD™) and the predicate device 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 MD™ is substantially equivalent to the predicate device.