Mirada Medical Ltd.
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd.
WARREN NJ 07059

April 15, 2022

Re: K220779
Trade/Device Name: XD
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: March 9, 2022
Received: March 17, 2022

Dear Dave Yungvirt:

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 and Part 809); 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,

For

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)*

K220779

Device Name

XD

Indications for Use *(Describe)*

Mirada XD is intended to be used by trained medical professionals including, but not limited to, radiologists, nuclear medicine physicians, and physicists.

Mirada XD is a software application intended to display and visualize 2D & 3D multi-modal medical image data. The user may process, render, review, store, print and distribute DICOM 3.0 compliant datasets within the system and/or across computer networks. Supported modalities include CT, PET, MR, SPECT and planar NM. Supported image types include static, gated and dynamic.

The user may also create, display, print, store and distribute reports resulting from interpretation of the datasets.

Mirada XD allows the user to register combinations of anatomical and functional images and display them with fused and non-fused displays to facilitate the comparison of image data by the user. The result of the registration operation can assist the user in assessing changes in image data, either within or between examinations and aims to help the user obtain a better understanding of the combined information that would otherwise have to be visually compared disjointedly.

Mirada XD provides a number of tools such as rulers and region of interests intended to be used for the assessment of regions of an image to support a clinical workflow. Examples of such workflows include, but are not limited to, the evaluation of the presence or absence of lesions, determination of treatment response and follow-up.

Mirada XD allows the user to define, import, transform, store and export regions of interest structures in DICOM RT format for use in radiation therapy planning 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.

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510(K) SUMMARY

(The following information is in conformance with 21 CFR 807.92)

510(k) Number	K220779
Date of summary:	12 Apr 2022
Submitter's name:	Mirada Medical Ltd
Submitter's address:	New Barclay House, 234 Botley Rd, Oxford OX2 0HP. United Kingdom United Kingdom
Submitter's contact:	Adam Taylor
Telephone number:	+44(0)1865 817600
Device Proprietary Name:	XD
Device Common Name(s):	XD, XD4, Mirada XD
Regulation Number	892.2050
Regulation Name	Medical Imaging and Processing System
Regulatory Class	Class II
Primary Product Code	LLZ

Predicate Device

510(k) Number	K101228
Trade Name	Mirada XD
Manufacturer	Mirada Medical Ltd
Device Name	Mirada XD
Regulation Number	892.2050
Regulation Name	Medical Imaging and Processing System
Regulatory Class	Class II
Primary Product Code	LLZ

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Reference Devices

The following reference devices are used within this submission to support the substantial equivalence discussion regarding performance evaluation. These devices have been selected as they share common features and technological characteristics with the proposed device.

510(k) Number	K102687
Trade Name	Mirada RT
Manufacturer	Mirada Medical Ltd
Device Name	Mirada RT
Regulation Number	892.2050
Regulation Name	Medical Imaging and Processing System
Regulatory Class	Class II
Primary Product Code	LLZ

510(k) Number	K130393
Trade Name	Mirada RTX
Manufacturer	Mirada Medical Ltd
Device Name	Mirada RTX
Regulation Number	892.2050
Regulation Name	Medical Imaging and Processing System
Regulatory Class	Class II
Primary Product Code	LLZ

1. Device Description

XD is a stand-alone desktop software application with tools and features designed to display or view medical images as well as tools for performing quantitative readings of the imaging data.

The use environment for XD is in a clinical environment, typically within dedicated radiology reading rooms or areas.

The software components provide functions for performing operations related to image display, manipulation, analysis, and quantification, including features designed to facilitate segmentation of user-defined regions of interest.

The software system runs on a dedicated workstation and is intended for display and processing, of a Computed Tomography (CT), Magnetic Resonance (MR), Positron Emission Tomography (PET), Single-Photon Emission Computed Tomography (SPECT) or Nuclear Medicine (NM) images, including contrast enhanced and dynamic or multisequence images.

XD is not intended for specific populations; the system can be used to display data of any patient demographic chosen by trained medical professionals including, but not limited to, radiologists, nuclear medicine physicians, and physicists for use in clinical workflows.

2. Indications for Use

Mirada XD is intended to be used by trained medical professionals including, but not limited to, radiologists, nuclear medicine physicians, and physicists.

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Mirada XD allows the user to define, import, transform, store and export regions of interest structures in DICOM RT format for use in radiation therapy planning systems.

3. Technical characteristic comparison

Characteristic	**XD**	**Mirada XD (K101228)**	**Equivalence**
510(k) number	Unknown	**K101228**	n/a
Classification	Class II. 892.2050 LLZ	Class II. 892.2050 LLZ	n/a
Target Population	XD is not intended for specific patient populations.	XD is not intended for specific patient populations.	Equivalent
Where Used	Used in non-sterile hospital environments such as radiology reading rooms and offices.	Used in non-sterile hospital environments such as radiology reading rooms and offices.	Equivalent
Energy Used and/or Delivered	None – software only application. The software application does not deliver or depend on energy delivered to or from patients	None – software only application. The software application does not deliver or depend on energy delivered to or from patients	Equivalent
Intended Users	Physicians	Physicians	Equivalent
Design: Supported modalities	CT, Gated CT, Multi-Phase CT MR, Dynamic MR, Multisequence MR Planar NM, PET, SPECT	CT, PET, MR, SPECT and planar NM.	Substantially Equivalent

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Design: Data Visualization	Window and level, pan, zoom, cross-hairs, slice navigation, thick slab.	Window and level, pan, zoom, cross-hairs, slice navigation	Substantially Equivalent
Design: Image Segmentation	Tools for segmenting 2D and 3D VOIs, including manual contouring, threshold-based segmentations and CT region segmentation (one-click seed-pointing contouring) using mutual information from the loaded image.	2D and 3D ROIs, semi-automatic ROI definition, iso-contour ROIs using threshold and percentage of maximum, one-click seed-pointing contouring, manual ROI manipulation.	Substantially Equivalent
Design: Image registration	Registration of multiple images, including multiple volumes (gated, multi-phase).	Registration of multiple images.	Substantially Equivalent
Design: Save images to PACS	Key images, secondary capture image stacks and report screen shots can be acquired which may be saved back to PACS or any DICOM nodes.	Key images, secondary capture image stacks and report screen shots can be acquired which may be saved back to PACS or any DICOM nodes.	Equivalent
Human Factors	Intended to be used safely and effectively by trained physicians and a human factors engineering process has been undertaken, adhering to IEC 62366-1:2015.	None. Mirada XD was developed before IEC 62366 was recognized as an FDA consensus standard.	n/a
Materials	Not applicable - software device only	Not applicable - software device only	n/a
Biocompatibility	Not applicable - software device only	Not applicable - software device only	n/a
Sterility	Not applicable - software device only	Not applicable - software device only	n/a
Electrical safety	Not applicable - software device only	Not applicable - software device only	n/a
Mechanical Safety	Not applicable - software device only	Not applicable - software device only	n/a
Chemical Safety	Not applicable - software device only	Not applicable - software device only	n/a
Thermal Safety	Not applicable - software device only	Not applicable - software device only	n/a

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Radiation Safety	Not applicable - software device only	Not applicable - software device only	n/a
Computer platform & operating system	Windows 10 Pro (64bit) Both physical workstations and virtual machines are supported.	Windows XP, Windows Vista, Windows 7	Substantially Equivalent
Labelling	Labelling complies with 21 CFR 801/830	Labelling complies with 21 CFR 801/830	Equivalent
Instructions for Use	Help Guide, Installation Guide, Release Notes	Help Guide, Installation Guide, Release Notes	Equivalent

4. Substantial Equivalence

When compared to the intended uses and indications listed for the predicate device and applicable to the proposed device, the proposed device is substantially equivalent to the predicate device.

Both devices provide similar tools with which to register, segment and quantify medical images for clinical workflows such as diagnosis and evaluation of treatment response.

The key differences between the predicate device and the proposed device is that the proposed device provides support for additional imaging data modalities as well as additional image visualization features and tools to semi-automatically segment regions of interest.

The additional visualization and segmentation features support the user in completing diagnostic readings and identifying potential findings. These features do not raise any new types of safety or effectiveness questions.

The above analysis of the characteristics of the XD and the Predicate Device demonstrate that the proposed device is substantially equivalent, and the differences do not affect safety or effectiveness.

There are no new indications for use for XD and therefore by following the FDA guidance document “The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]”, XD is determined to be substantially equivalent to the predicate device.

5. Performance

XD is validated and verified against its user needs and intended use by the successful execution of planned performance, functional and algorithmic testing included in this submission.

The results of performance, functional and algorithmic testing demonstrate that XD meets the user needs and requirements of the device, which are considered to be substantially equivalent to those of the listed predicate device.

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Test planning was performed in accordance with standard testing procedures and guidelines as listed in internal development processes.

Human factors testing has been performed in line with Applying Human Factors and Usability Engineering to Medical Devices, February 3, 2016 and IEC 62366-1:2015.

Verification and validation testing were carried out as per planned arrangements in the Project Test Plan and Phase Test Plan(s) to ensure that design outputs meet design inputs and that this edition of XD meets the product acceptance criteria. These are in accordance with the company's Design Control process in compliance with 21 CFR Part 820.30, which included testing that fulfills the requirements of FDA "Guidance on Software Contained in Medical Devices" and adherence to the DICOM standard.

Potential risks were analyzed and satisfactorily mitigated in the device design.

Performance testing (Bench) was performed, including on the following features, to ensure that performance and accuracy was as expected:

- Thick Slab visualization
- PET hotspot finder

XD provides functions including linear distance measurements and volumetric measurements. The resolution of the medical image data directly affects the ability of the user to make definitive measurements, especially when the sizes of structures to identify, segment or measure are near the resolution of the image data. The software's functions are dependent on the user actions as well as on the available information in the provided medical image data.

Segmentation tools provided within XD include manual and semi-automated segmentation. The use of the segmentation tools to achieve a satisfactory delineation of any regions of interest is a user operation and the clinical accuracy of segmentation is the responsibility of the user and not an XD function.

Registration tools provided within XD automatic rigid registration and automatic deformable image registration. Registrations can be applied to combinations of anatomical and functional images and then displayed as fused views.

XD can perform calculations of Standard Uptake Values from conventional PET images. XD provides multiple options for the quantification algorithms which can be selected by the user dependent on available data in the original DICOM file.

Input DICOM data places limits on the accuracy of all values displayed within XD. This includes spatial measurements such as linear distances, angles and volume (all limited by the accuracy of the original input data), voxel intensity information, and derived values calculated from these including SUV measures and statistical measures on regions of interest (including comparison ratios to other regions, e.g. for PERCIST measurements). In the case of SUV values, user-entered or user-modified values for patient information (e.g. height, weight) will also affect the accuracy of the final result.

It is the responsibility of the user to determine if the results of image visualization are satisfactory and allow the accurate use of the functions provided.

6. Standards and guidelines

XD complies to the following FDA recognized standards:

- IEC 62304:2006+A1:2015 Medical device software - Software life cycle processes

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- IEC 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices
- ISO 14971:2019 Medical devices - Application of risk management to medical devices
- NEMA PS 3.1 - 3.20 (2016) DICOM 3.0 Digital Imaging and Communications in Medicine (DICOM) Set

The following other Standards were used during development of XD:

- ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes

The following guidelines were used during development of XD:

- "How to Prepare a Traditional 510(k)" and "eCopy Program for Medical Device submissions" dated April 27, 2020.
- The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications 510(k), July 28, 2014
- Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions, December 20, 2019.
- Applying Human Factors and Usability Engineering to Medical Devices, February 3, 2016
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, October 2, 2014.
- Guidance for the content of premarket submissions for software contained in medical devices, May 11, 2005
- Format for Traditional and Abbreviated 510(k)s, September 13, 2019.
- Deciding When to Submit a 510(k) for a Software Change to an Existing Device, October 25, 2017.

7. Conclusion

In conclusion, performance testing demonstrates that XD is substantially equivalent to, and performs at least as safely and effectively as, the listed predicate device. XD meets requirements for safety and effectiveness.

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