



Mirada Medical Ltd.  
% Mark Job  
Responsible Third Party Official  
Regulatory Technology Services, LLC  
1394 25<sup>th</sup> Street, NW  
BUFFALO MN 55313

April 22, 2020

Re: K181572  
Trade/Device Name: Workflow Box  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: Class II  
Product Code: QKB

Dear Mr. Job:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated (07.10.2018). Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Julie Sullivan, OHT7: Office of In Vitro Diagnostics and Radiological Health, 240-402-4973, [Julie.Sullivan@fda.hhs.gov](mailto:Julie.Sullivan@fda.hhs.gov).

Sincerely,

For

Thalia T. Mills  
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



Mirada Medical Ltd.  
% Mr. Mark Job  
Responsible Third Party Official  
Regulatory Technology Services, LLC  
1394 25th Street, NW  
BUFFALO MN 55313

July 10<sup>th</sup>, 2018

Re: K181572

Trade/Device Name: Workflow Box  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: II  
Product Code: LLZ  
Dated: June 12, 2018  
Received: June 14, 2018

Dear Mr. Job:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



for  
Robert Ochs, Ph.D.  
Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K181572

Device Name  
Workflow Box

### Indications for Use (Describe)

Workflow Box is a software system designed to allow users to route DICOM-compliant data to and from automated processing components. Supported modalities include CT, MR, RTSTRUCT

Workflow Box includes processing components for automatically contouring imaging data using deformable image registration to support atlas based contouring, re-contouring of the same patient and machine learning based contouring.

Workflow Box is a data routing and image processing tool which automatically applies contours to data which is sent to one or more of the included image processing workflows. Contours generated by Workflow Box may be used as an input to clinical workflows including, but not limited to, radiation therapy treatment planning.

Workflow Box must be used in conjunction with appropriate software to review and edit results generated automatically by Workflow Box components, for example image visualization software must be used to facilitate the review and edit of contours generated by Workflow Box component applications.

Workflow Box is intended to be used by trained medical professionals.

Workflow Box is not intended to automatically detect lesions.

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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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 of Safety and Effectiveness

<b>Date of summary:</b>	9 <sup>th</sup> July 2018
<b>Submitter's name:</b>	Mirada Medical Ltd
<b>Submitter's address:</b>	Oxford Centre for Innovation, New Road, Oxford. Oxfordshire, OX1 1BY United Kingdom
<b>Submitter's contact:</b>	Gwilym Owen
<b>Telephone number:</b>	+44 (0)1865 261410
<b>Device Proprietary Name:</b>	Workflow Box™ (including DLCExpert™, Embrace:CT™, Embrace:MR™, Re:Contour™)
<b>Device Common Name(s):</b>	Workflow Box
<b>Classification Name:</b>	Class II: Picture Archiving and Communications System (892.2050) Product Code: LLZ

Workflow Box is Substantially Equivalent to the following Legally Marketed device:

### Predicate Devices

<b>510(k) Number</b>	<b>Trade Name</b>	<b>Manufacturer</b>
K130393	Mirada RTx	Mirada Medical Ltd.

### Intended Use

Workflow Box is a system designed to allow users to route DICOM-compliant data to and from automated processing components.

Workflow Box includes processing components for automatically contouring imaging data using deformable image registration and machine learning based algorithms.

Workflow Box must be used in conjunction with appropriate software to review and edit results generated automatically by Workflow Box components, for example image visualization software must be used to facilitate the review and edit of contours generated by Workflow Box component applications.

Workflow Box is not intended to automatically detect lesions.

### Device Description

Workflow Box is a software application that enables the routing of image data and structures to automatic image processing workflows, including atlas based contouring, image registration based re-contouring and machine learning based contouring.

Workflow Box data routing and contouring workflows support CT, MR and RTSTRUCT image data and structures. Workflow Box supports the routing of data to and from DICOM nodes within a hospital network.

Once data is routed to the auto contouring workflows there is no user interaction required and no user interface for visualizing image data. The configuration of workflows and data routing rules are managed via an administration interface.

Workflow Box must be used in conjunction with appropriate software to review and edit results generated automatically by Workflow Box components. Image visualization software, such as a treatment planning system, must be used to facilitate the review and edit of contours generated by Workflow Box component applications.

### Indications for Use

Workflow Box is a software system designed to allow users to route DICOM-compliant data to and from automated processing components. Supported modalities include CT, MR, RTSTRUCT

Workflow Box includes processing components for automatically contouring imaging data using deformable image registration to support atlas based contouring, re-contouring of the same patient and machine learning based contouring.

Workflow Box is a data routing and image processing tool which automatically applies contours to data which is sent to one or more of the included image processing workflows. Contours generated by Workflow Box may be used as an input to clinical workflows including, but not limited to, radiation therapy treatment planning.

Workflow Box must be used in conjunction with appropriate software to review and edit results generated automatically by Workflow Box components, for example image visualization software must be used to facilitate the review and edit of contours generated by Workflow Box component applications.

Workflow Box is intended to be used by trained medical professionals.

Workflow Box is not intended to automatically detect lesions.

### Comparison of Indications for Use with Predicate Device

Both the proposed device and the predicate device are software devices designed to be used by trained medical professionals within a hospital environment and are indicated for the creation of contours for use in clinical workflows including radiation therapy treatment planning.

The proposed device and the predicate device both utilize deformable image registration to support one or more of the workflows they perform and facilitate the transformation of region of interest structures/Contours.

The proposed and predicate device both allow the clinician to load existing contour sets and associated planning volumes and transform them to a new planning volume using rigid and non-rigid registration as part of a re-planning/re-contouring workflow.

The proposed and predicate device both utilize an atlas based technique for the automated delineation of structures on CT.

The proposed and predicate device are both designed to interoperate via DICOM objects and networking with other DICOM capable devices such as PACS and Radiation Treatment Planning Systems.

The predicate device is intended to display and visualize image data and enables a comparison of image data by the user, whereas the proposed device does not facilitate the display or visualization of data by the user.

The review and editing of contouring results can be performed within the predicate device where a different image visualization system is needed to perform the review and edit of contours generated by the proposed device, however both the predicate and proposed device require users to confirm and review output in a different system. The proposed device is intended for a sub-set of the intended use of the predicate device where the image visualization and comparison purpose of the predicate device is not applicable to the proposed device.

Therefore, the intended use of the proposed device is substantially equivalent to the predicate device, excepting the image visualization features in the predicate device which are not applicable to the proposed device.

### Comparison of Technological Characteristics with Predicate Device

Characteristic	Workflow Box	predicate
Target Population	Any patient type for whom relevant modality scan data is available.	Any patient type for whom relevant modality scan data is available.
Where Used	Clinical/Hospital environment	Clinical/Hospital environment
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(s) do not deliver or depend on energy delivered to or from patients
Human Factors	Designed to be used by trained clinicians	Designed to be used by trained clinicians
Design: Data Visualisation/Graphical User Interface	None – the proposed device has no data visualization functionality. All data processing is automated and does not require user interaction. A control interface is provided for system administration and configuration only.	Yes
Design: View manipulation and Volume rendering	None – Not applicable	Window and level, pan, zoom, cross-hairs, slice navigation.  Maximum or minimum intensity projection (MIP), volume rendering, color rendering, surface rendering, multi-planar reconstruction (MPR), fused views, gallery views.
Design: Image registration	Registration for the purposes of re-planning/re-contouring and atlas based contouring. The algorithms used for image	Manual and Landmark Rigid. Automatic multi-modal rigid. Mono-modal and multi-modal deformable

	registration are the same for both predicate and proposed devices.	registration. Motion correction in hybrid scans and gated scans.
		Registration for the purposes of re-planning/re-contouring and atlas based contouring.
Regions and Volumes of interest (ROI)	Atlas Based contouring, registration based re-contouring, machine learning based contouring	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, ROI transformation, Atlas-based contouring.
Design: Region/volume of interest measurements and size measurements	None – not applicable	Intensity, Hounsfield units, activity and SUV measurements including min, max, mean, peak, standard deviation, total glycolytic activity, median, histogram, max and mean ratio to reference region. Gray for RT Dose.  Size measurements include 2D and 3D measurements including rulers and volume, line profile.
Design: Region/Volume Quantification	None – not applicable	Regions table with charting supports analysis of measurement over multiple studies using standard protocols such as RECIST, PERCIST and WHO
Design: Supported modalities	CT, MR, DICOM RTSTRUCT for image processing  Any valid DICOM data for data routing	Static and gated CT and PET, and static MR, SPECT, NM, DICOM RT
Design: Reporting and data routing	Supports routing and distribution of images to other DICOM nodes including to custom executables determined by the user.	Yes– Distribution of DICOM compliant Images into other DICOM compliant systems.  Built-in basic reporting
Compatibility with the environment and other devices	Compatible with data from any DICOM compliant scanners for the applicable modalities.  Compatible with Microsoft Windows  Integration with Mirada DBx application launcher and data browser	Compatible with data from any DICOM compliant scanners for the applicable modalities.  Compatible with Microsoft Windows  Integration with Mirada DBx application launcher and data browser
Communications/ Networking	TCP/IP and SCP	TCP/IP and SCP
Computer platform & operating system	Server based application supporting Microsoft Windows 10 (64-bit) and Microsoft Windows Server 2016.	Workstation and Server based application supporting Windows Server 2008 R2, SP1 and Windows 7 (64-bit)

The predicate device and Workflow Box are both standalone software applications for medical image processing. Both devices process DICOM image data and include design features to enable automatic delineation of contours on input image data.

Both the proposed device and the predicate device utilize algorithms to automatically generate region of interest structures/contours. Both devices utilize image registration for the purposes of atlas based contouring and re-contouring.

The automatic image processing tools are the same in both devices where image registration is used to apply contours to image data.

In addition to automatic image processing, the predicate device offers manual image manipulation, processing and quantification tools which are not applicable to Workflow Box.

Both devices are compatible with the same use environments and utilize the same networking technology and operate on similar operating systems.

Workflow Box offers a sub-set of the automated image processing technical features presented by the predicate device. These features are substantially equivalent to the predicate device and do not present any addition or new risks when compared to the predicate device.

## Testing

Workflow Box 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 Workflow Box meets the user needs and requirements of the device, which are demonstrated to be substantially equivalent to those of the listed predicate device.

Verification and Validation for Workflow Box has been carried out in compliance with the requirements of CFR 21 Part 820 and in adherence to the DICOM standard.

## Conclusion

In conclusion, performance testing demonstrates that Workflow Box is substantially equivalent to, and performs at least as safely and effectively as the listed predicate device. Workflow Box meets requirements for safety and effectiveness and does not introduce any new potential safety risks.