

16072242

**510(k) Summary of Safety and Effectiveness** (in accordance to 21 CFR 807.87(h))

**Device Name**

Proprietary Device Name: COR Analyzer II

**Establishment Name and Registration Number of Submitter**

Name: RCADIA Ltd. (RCADIA hereafter)

Registration: In process

Submission contact: Dan Laor

Sireni 6, Haifa 32972, Israel

TEL: 972-4-8246632

SEP 11 2007

**Device Classification**

**Product Code:** LLZ

**Subsequent Product Code:** JAK

**Regulation Number:** 892.2050

**Common Name:** PACS - Picture archiving & communications system

**Classification Name:** Picture archiving and communications system

**Regulatory class:** Class II

**Reason for 510(k) Submission**

Special 510(k) Submission

**Identification of Legally Marketed Equivalent Devices**

K061624 *Vitrea2*, K063548 COR Analyzer I

**Device Description**

COR Analyzer I is a post processing software application which runs on a stand-alone Windows based work-station. The device input is Computed Tomography Angiography (CTA) set of images. The received data is displayed on the workstation screen, reviewed and selected by the operator for processing. Software provides the location and segmentation of the coronary artery tree. The software also labels the coronary arteries and displays them uniquely colored in a 3D view. The artery changes of volumes are processed and deviations from expected values are detected. When a deviation exceeds threshold value it is displayed on the 3D view.

**Indications for use**

The COR Analyzer II is intended to assist a trained physician to analyze Computed Tomography (CT) Angiographic images. The device is not intended for use with mammography. The COR Analyzer II is specifically indicated to provide visualization of the major coronary vessels and lesions, thus assisting the physician in visualizing the coronary anatomy and pathology. COR Analyzer II has abilities for coronary vessels segmentations, abnormalities display and processing.

**Safety & Effectiveness**

The device has been designed, verified and validated complying with 21CFR 820.30 regulations. Bench and clinical data demonstrate that the COR Analyzer II meets the required specifications. No adverse affects have been detected.

**Substantial Equivalency**

It is Rcadia Medical Imaging Ltd. opinion that the COR Analyzer II is substantially equivalent in terms of indications for use, safety and effectiveness to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
9200 Corporate Blvd.  
Rockville MD 20850

RCADIA Medical Imaging, Ltd.  
% Mr. Dan Laor  
Managing Director  
Quasar Quality Ltd.  
6 Sireni  
Haifa  
Israel 32972

SEP 11 2007

Re: K072242

Trade/Device Name: COR Analyzer II  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: II  
Product Code: LLZ  
Dated: August 12, 2007  
Received: August 13, 2007

Dear Mr. Laor:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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.



*Protecting and Promoting Public Health*

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); 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.

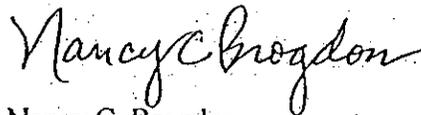
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known):

Device Name: COR Analyzer II

### Indications For Use:

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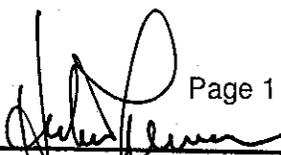
Prescription Use  AND/OR  
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
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(Division Sign-Off)  
Division of Reproductive, Abdominal, and  
Radiological Devices  
510(k) Number K072242