FEB 16 2012

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

Device Name

Proprietary Device Name: 3Di including Viewing of Mammography images

Establishment Name and Registration Number of Submitter

Name: Shina Systems Ltd.
Corresponding Official: Dan Laor
Sireni 6, Haifa 32972, Israel TEL: +972-4-8246632

Device Classification

Product Code:	LLZ
CFR section:	892.2050
Panel Identification:	Radiology
Device Description:	Picture archiving and communications system
Classification:	II

Reason for 510(k) Submission

Traditional 510(k) Submission

Identification of Legally Marketed Predicate Devices

K112530 3Di

Device Description

3Di is a PACS device which enables users to access medical images over a network and to utilize 3Di's image visualization tools to review the images. It provides the following functions: Web server, patient browser, PACS capabilities, multi-modality viewing, CT Cardiac and Colonoscopy clinical applications. The 3Di indications for use have been modified to include viewing of Mammography images.

Intended use and indications for Use

3Di is a software package of PACS workstation for handling multimodality (CT, XA, MR, PET, SPECT, Ultrasound &Mammography) images, which are using DICOM protocol. It includes volume rendering, Multi-planar reconstruction (MPR) and viewing of the inner and outer surfaces of organs as well as within their walls. 3Di is intended for use as an interactive tool for assisting professional Radiologists, Cardiologists and specialists to reach their own diagnosis, by providing tools of communication, clinics networking, WEB Serving, image viewing, image manipulation, 2D/3D image visualization, image processing, reporting and archiving. The 3Di indications for use are processing of Cardiac CT studies, including CT Calcium scoring, CT Cardiac angiography, coronaries analysis, cardiac functional assessment and of CT colonoscopy.

Safety & Effectiveness

The device has been designed, verified and validated complying to 21CFR 820.30 regulations. The device has been designed to meet the requirements of ISO 14971 Safety standard. The quality of Mammography imaging has been validated by comparison the device imaging output to the DICOM source mammographic data. The comparison results demonstrate that the 3Di and the DICOM source mammographic data are substantial equivalent in terms of image quality.

Substantial Equivalency

It is Shina System opinion that the 3Di is substantially equivalent in terms of safety and effectiveness to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

FEB 16 2012

Shina Systems Ltd.
% Mr. Dan Laor
Quality and Regulatory Advisor
Sireni 6
32972 HAIFA
ISRAEL

Re: K113442
Trade/Device Name: 3Di
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 9, 2011
Received: November 21, 2011

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113442

Device Name: 3Di

Indications For Use:
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Prescription Use **X** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K113442