K100372

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

Device Name
Proprietary Device Name: SafeCT

Establishment Name and Registration Number of Submitter
Name: Medic Vision Brain Technologies Ltd.
Corresponding Official: Dan Laor
Sireni 6, Haifa 32972, Israel
TEL: 972-4-8246632

DEC 14 2010

Device Classification

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

Reason for 510(k) Submission
Traditional 510(k) Submission

Identification of Legally Marketed Predicate Device
K024028 SharpView, manufactured by ContextVision

Device Description
The SafeCT is a software package of a PACS server, which is connected to the clinics' Local Area Network (LAN), receives, processes and transfers CT images, using the DICOM protocol. The processing enhances image quality by reduction of the image noise.

Intended use and Indications for Use
The SafeCT is intended for networking, communication, processing and enhancement of CT images in DICOM format. It is specifically indicated for assisting professional radiologists and specialists in reaching their own diagnosis. The device processing is not effective for lesion, mass or abnormalities of sizes less than 3 mm The SafeCT is not intended for use with or for diagnostic interpretation of Mammography images

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. Its performance has been validated by comparing the image quality of phantom and clinical processed data to the image quality of the original (unprocessed) corresponding data. The results of the performance testing demonstrate the device safety and effectiveness.

Substantial Equivalency
It is Medic Vision opinion that the SafeCT 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

Medic Vision Imaging Solutions, Ltd.
% John J. Smith, M.D., J.D.
Partner
Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
WASHINGTON DC 20004

DEC 14 2010

Re: K100372
Trade/Device Name: SafeCT
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 18, 2010
Received: November 19, 2010

Dear Dr. Smith:

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 (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

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,

David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use K100372

DEC 14 2010

510(k) Number (if known):

Device Name: SafeCT

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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)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K100372