DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

May 17, 2016

Medic Vision Imaging Solutions Ltd.
% Mr. Dan Laor
Q&R Advisor
6 Sireni St.
Haifa, 32972
ISRAEL

Re: K153331
Trade/Device Name: SafeCT-29
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: April 11, 2016
Received: April 19, 2016

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. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K 153331

Device Name
SafeCT-29

Indications for Use *(Describe)*
The SafeCT-29 is intended for providing Computed Tomography Dose Check feature to Computed Tomography X-ray systems.
The SafeCT-29 is specifically indicated for providing the Computed Tomography Dose Check feature which notifies and alerts the CT equipment operators, prior to a scan, if the estimated dose index is above the predefined thresholds, for CT scanners not equipped with this functionality. The device is indicated for use by professional personnel.

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.

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510(k) Summary

Submitter details

Medic Vision Imaging Solutions Ltd.
3 Yozma St, Tirat Carmel 39032, Israel Telephone +972.73.7262226

Submission Contact: Dan Laor 6 Sireni St., Haifa, 32972, Israel.
Preparation Date: March 16, 2016

Details of the submitted Device

Proprietary Name:	SafeCT-29
Regulation Number	892.1750
Product Code:	JAK
Committee/Panel:	Radiology
Device Class:	2

Reason for 510(k) Submission:

New Device

Identification of the Legally Marketed Predicate Device

Proprietary Name:	*syngo* ® VA48 (SOMARIS/7 VA48)	K143400
Regulation Number	892.1750	
Product Code:	JAK	
Committee/Panel:	Radiology	
Device Class:	2	

Device Description

Medic Vision's SafeCT-29 provides a vendor-neutral Radiation Dose Check functionality, in accordance with the Dose Check feature that is specified by the NEMA XR-25 Standard. The device is a software and hardware system which includes Computer, dedicated display and controls. The SafeCT-29 is interfaced to CT scanners that are not equipped with the Dose Check function. The device is connected to the CT Console video output via a standard video connector. The SafeCT-29 Computer's internal video splitter captures the CT Console display video, in real time, without affecting neither the CT console itself nor its display. This analog video signal is digitized by a video grabber. The SafeCT-29 software analyzes the digital input video using OCR software continuously. The radiation dose information as calculated by the scanner and displayed to the CT operator is extracted and analyzed in real time. The SafeCT-29 captures the video of the CT Console display in real time, without affecting neither the CT console itself nor its display and workflow. As specified by NEMA XR-25 Standard, the safeCT-29 notifies and alerts the CT operators, prior to a scan, if the estimated dose index is above the predefined values set by the operating group, practice, or organization. SafeCT-29 prevents continuing an over-the-limit scan unless dose levels are reconfirmed by the operator, in accordance with NEMA XR-29*.The device records the details of such events, including the operator details and decisions. This record is available to the user.

*The SafeCT-29 does not provide all the features specified in the NEMA XR-29 standard. The only provided feature is the Dose Check**.**

Intended use and indications for Use

The SafeCT-29 is intended for providing Computed Tomography Dose Check feature to Computed Tomography X-ray systems.
The SafeCT-29 is specifically indicated for providing the Computed Tomography Dose Check feature which notifies and alerts the CT equipment operators, prior to a scan, if the estimated dose index is above the predefined thresholds, for CT scanners not equipped with this functionality. The device is indicated for use by professional personnel.

Substantial Equivalence information

Reference guidance documents

- "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", May 11 2005
- "Guidance on Off-the-Shelf Software Use in Medical Devices" September 9, 1999.

Comparison with the predicate device

Intended Use: As the predicate device, the SafeCT-29 is intended to provide Computed Tomography Dose Check feature to Computed Tomography X-ray systems.

Indications for Use: As the predicate device, the safeCT-29 is indicated for use by authorized personnel to provide the Computed Tomography Dose Check feature which notifies and alerts the CT equipment operators, prior to a scan, if the estimated dose index is above the predefined thresholds.

Differences in Technological Characteristics

Category	**Predicate Device** Syngo® VA48	**Subject Device** SafeCT-29
Data inputs	Host CT Digital Data directly interfaced by the device software.	The SafeCT-29 uses its own input separate hardware: The device is interfaced to the CT screen via a video splitter that provides a copy of the CT screen in real-time. The CT screen data is captured by grabbing and digitizing the video signal. The captured data is interpreted by OCR software.
Scan Controls	Software	Software & hardware
Accumulates values for the total CTDIvol	Designed to fulfill the requirements of the NEMA XR-25 Standard section 2.2.2	The software extracts accumulated CTDIvol per Z axis location from the CT screen whenever such information is displayed by the scanner. For scanners that do not present such information, the accumulated CTDIvol is calculated by the SafeCT-29 software. The calculation follows the AAPM guidelines and assumes “worst case scenario” (i.e. calculated

		CTDIvol may be higher than the actual value) in order to prevent over-the-limit scans. The SafeCT-29 assumes that each z-axis position gets the displayed maximum CTDIvol value, and calculates the accumulated CTDIvol accordingly.
Display	Host CT Screen	The SafeCT-29 has its own display separate hardware: a dedicated monitor. SafeCT-29 generates an audio alert to ensure the user is aware of notifications and warnings displayed on its display.
Man machine interface	Host CT keyboard & mouse	Dedicated keyboard & mouse
Record Data output	Not known	Data is saved in the Device's internal memory and can be exported with a USB memory stick
Processor hardware	Host CT Processor	Dedicated Off-the-shelf processor and controls

The effects of the difference in Data inputs

(a) The SafeCT-29 specificity in detecting the correct input data (protocol and dose data) is 99%*.

* This value was obtained by the OTS verification process - see Design Verification below.

(b) The SafeCT-29 delay in detecting the correct input data is less than 300ms, which is negligible in terms of man machine interface time.

Verification and Validation

Design Verification: In conformance to the requirements of 21CFR 820.30 (f), Medic Vision established and maintains procedures, which confirm that the design output meets the design input requirements. The design verification testing details, including identification of the design and methods are as follows:

The device software has been verified by testing the software following predefined software test plan, which confirmed that the software output meets the input as defined by the Software Requirements Specifications (SRS). The SRS encompasses Dose Check features as specified by NEMA XR-25 standard, display & operation controls and applicable risk mitigations. The test results were recorded and traceability control was established to ensure the all the SRS requirement were met.

An Off-The Shelf (OTS) OCR software which is embedded in the SafeCT-29 software has been verified by testing its performances following the requirements of the "Guidance on Off-the-Shelf Software Use in Medical Devices". As required by the guidance the OTS performance was tested prior to mitigation and after embedding it into the SafeCT-29 software and taking mitigation means. Before the test, 1800 screen images were captured from various CT scanners. These images included more than 6000 numeric and alphanumeric text images.

These data were input into the device and the dose levels and protocols were calculated based on the software analysis and recognition of the numeric and alphanumeric text images. The results were compared to the original CT screens' data. The resulted specificity in detecting the correct input data (protocol and dose data) was better than 99.4%. These test results confirmed that, after mitigation, the OTS performance meets the system software requirements.

The performance of the SafeCT-29 system has been verified by simulation methods. Sequence of data, which were recorded from various CT scanners, served as the SafeCT-29 input. The data was processed by the device and its Dose Check functionality was tested. The results of process confirmed that device meets its performance specifications. Additionally, the usability and reliability of the SafeCT-29 system was verified in user environment at 4 imaging centers, using 4 different CT scanner models, by end-users and Medic Vision engineers.

Design Validation: In conformance to the requirements of 21CFR 820.30 (g), Medic Vision established and maintains procedures, which ensure that devices conform to defined user needs and intended uses. The validation process included testing of production units. This testing was performed at end-user operating conditions in five medical centers with five different CT scanner models. The tests included the device installation, operation, functionality processes and features. The test results confirmed that the SafeCT-29 meets the defined user needs and intended uses.

The above verification and validation testing methods adhered to state-of-art standards and procedures.

Clinical Data:

Clinical data is not included (not applicable).

Risk Management

The device risks were managed and controlled following the requirements of ISO 14971standard. The device hazards were identified, their risk levels were evaluated and mitigation measures were taken to reduce the risk levels. In Medic Vision opinion the benefits of providing the Dose Check feature to CT scanners not equipped with this function, overweight the device residual risks.

The SafeCT-29 is designed to fulfill the requirements of the following standards:

- IEC60601-1:2005+CORR. 1 (2006) + CORR. 2 (2007) - Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
- EN 60601-1-2 :2007 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests