DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 28, 2017

Zetta Medical Technologies, LLC.
Main M. Ghazal
President
1313 Ensell Road
Lake Zurich, Illinois 60047

Re: K170273
Trade/Device Name: Z-DOSE29
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: January 30, 2017
Received: January 30, 2017

Dear Main Ghazal:

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,

For

Robert A. 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)*
K170273

Device Name
Z-DOSE29

Indications for Use *(Describe)*
Z-DOSE29 Dose Check system is intended to provide dose check features to Computed Tomography systems. Z-DOSE29 software extracts CTDI values from CT host computer's screen, compares it to predefined thresholds, and sends notification and alert messages to the CT scanner display monitor prior to scanning.

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 of Safety and Effectiveness

1. Applicant & Submitted By:
Zetta Medical Technologies, LLC.
1313 Ensell Road, Lake Zurich, IL 60047
Phone: (847) 550-9990
Fax: (847) 550-9994
Contact Person: Main M. Ghazal, President
Date Prepared: January 22nd 2017

2. Identification of the Device:
Trade Name: Z-DOSE29
Common Name: Computed Tomography X-ray system
Classification Name: 21 CFR, 892.1750, JAK, Radiology

3. Predicate Device:

Manufacturer	Trade name/model	510(k) Number	Regulation Number	Product code
Siemens	syngo ® VA48 (SOMARIS/7 VA48)	K143400	892.1750	JAK
Medic Vision	SafeCT-29	K153331	892.1750	JAK

4. Indications for Use:
Z-DOSE29 Dose Check system is intended to provide dose check features to Computed Tomography systems. Z-DOSE29 software extracts CTDI values from CT host computer's screen, compares it to predefined thresholds, and sends notification and alert messages to the CT scanner display monitor prior to scanning.

5. Device Description:
Z-DOSE29 Dose Check provides the Dose Check feature to CT scanners as specified by the NEMA XR-25 standard and the Dose Check feature of NEMA XR-29*. This includes both Dose Notifications (for individual series) and Dose Alerts (for accumulated dose).

The Z-DOSE29 Dose Check software, which is installed on a remote computer that resides on the same local area network as the CT host computer, receives DICOM images from the CT host computer. The software captures CTDI values for each prescribed CT series, compares the values to AAPM dose check guideline (version 1.0) values and displays notification message(s) on the CT scanner operator's console. The Z-DOSE29 Dose Check software also adds the CTDI values from the individual series and displays alert message(s) on the CT scanner operator's console if the accumulated CTDI value exceeds a predefined ALERT threshold.

*NEMA XR-29 incorporates NEMA XR-25 Dose Check feature

In the event of an Alert, and in addition to displaying the alert message to the CT operator, Z-DOSE29 utilizes a relay to disable scanning until a correct password is inputted by the CT operator.

The Z-DOSE29 Dose Check software also records CTDI values and CT exam information into a local a database. Information in the database can be accessed by authorized users via a web browser.

The Z-DOSE29 Dose Check software runs on a Windows operating system 10 with a .net framework 4.0 or higher version.

6. Substantial Equivalence Table

The subject device Z-DOSE29 Dose Check System is substantially equivalent to the two predicate devices, Syngo® VA48 and SafeCT-29. Detailed comparison of Z-DOSE29 with SingoVA48 and SafeCT-29 is listed in Table-1.

Table -1: Comparison among Z-DOSE29, Syngo® VA48 and SafeCT-29 CT Dose Check Systems

Characteristics	Z-DOSE29	Syngo® VA48	SafeCT-29
Indications for Use	Z-DOSE29 Dose Check system is intended to provide dose check features to Computed Tomography systems. Z-DOSE29 software extracts CTDI values from CT host computer's screen, compares it to predefined thresholds, and sends notification and alert messages to the CT scanner display monitor prior to scanning.	The Siemens SOMATOM Definition AS/ AS+ (Project P46) systems are intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes* taken at different angles. (*spiral planes: the axial planes resulted from the continuous rotation of detectors and x-ray tube, and the simultaneous translation of the patient.)	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.
Data Inputs	Z-DOSE29 is a software based solution to extract CTDI information from CT computer's screen through a	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

Characteristics	Z-DOSE29	Syngo® VA48	SafeCT-29
	local area network (LAN) connection.		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 and hardware	Software	Software & hardware
Dose Notification for individual series	Designed to perform the "Dose Notification" feature of NEMA XR-25	Designed to perform the "Dose Notification" feature of NEMA XR-25	Unknown
Dose Alert for accumulated CTDI	Designed to perform the "Dose Alert" feature of NEMA XR-25	Designed to perform the "Dose Alert" feature of NEMA XR-25	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	Host CT Screen	The SafeCT-29 has its own external display monitor as a separate hardware. SafeCT-29

Characteristics	Z-DOSE29	Syngo® VA48	SafeCT-29
			generates an audio alert to ensure the user is aware of notifications and warnings displayed on the SafeCT-29 display monitor.
Man machine interface	Host CT keyboard & mouse	Host CT keyboard & mouse	SafeCT-29 own dedicated keyboard & mouse
Record data output	Data is saved in a local database, which can be accessed by authorized users via a web browser. Data can also be exported to excel files.	Not known	Data is saved in the Device's internal memory and can be exported with a USB memory stick
Processor hardware	Off-the-shelf computer	Host CT Processor	Dedicated Off-the-shelf processor and controls

Z-DOSE29 CT Dose Check system has similar indications for use as predicate device. The main difference is that the predicate devices employ either same CT host computer or a separate computer, that receive video signal from CT host screen for notifications, while Z-DOSE29 uses a remote computer on the same LAN as CT host computer for notifications and alerts. Performance testing, along with verification and validation activities demonstrate that Z-DOSE29 is as safe and effective as predicate device.

7. Performance Testing:

Z-DOSE29 has been designed, verified and validated in compliance with FDA 21 CFR Part 820 requirements. Z-DOSE29 software uses off-the-shelf software (OTS) to capture and extract CTDI information from CT host computer. Testing performed on OTS using more than 2400 image data sets indicated that OTS accurately extracts CTDI information from more than 99% of the images. The CT operator can manually input the CTDI values into the software in the event the software doesn't read the correct CTDI value. Z-DOSE29 was verified to meet system requirement specifications (SRS) on four different CT scanners from different manufacturers (test results summary shown in Table-2 below) and lower level requirements were verified on 9 different systems.

Reference Guidance Documents

- National Electrical Manufacturers Association, "NEMA Standards Publication XR 25-2010 Computed Tomography Dose Check"
- National Electrical Manufacturers Association, "NEMA Standards Publication XR 29-2013 Standard Attributes on CT Equipment Related to Dose Optimization and Management" Section 2.3
- "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
- "Guidance for the Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" October 2, 2014

Table -2: Z-DOSE29 system level verification and validation summary

Requirement	Expected outcome	Scanners used for testing	Observed outcome	Test result
SRS.001 Notification during **Adult Head** exam	The software captures the CTDI value for **Adult Head** and compares it to AAPM Dose Check Guidelines suggested threshold value (Default Value). If the value exceeds the threshold value, the software notifies the user by displaying a dialogue box. The dialogue box contains both captured CTDI value as well as the threshold value applied. The threshold value is configurable by the user in a text file.	GE Light Speed 32; Siemens Sensation 16; Philips Brilliance 64; Toshiba Aquilion 64;	The software captured the CTDI value for **Adult Head** and compared it to AAPM Dose Check Guidelines suggested threshold value (Default Value). If the value exceeded the threshold value, the software notified the user by displaying a dialogue box. The dialogue box contained both captured CTDI value as well as the threshold value applied. The threshold value is configurable by the user in a text file.	PASS
SRS.001 Notification during **Adult Body** exam	The software captures the CTDI value for **Adult Body** and compares it to AAPM Dose Check Guidelines suggested threshold value (Default Value). If the value exceeds the threshold value, the software notifies the user by displaying a dialogue box. The dialogue box contains both captured CTDI value as well as the threshold value	GE Light Speed 32; Siemens Sensation 16; Philips Brilliance 64; Toshiba Aquilion 64;	The software captured the CTDI value for **Adult Body** and compared it to AAPM Dose Check Guidelines suggested threshold value (Default Value). If the value exceeded the threshold value, the software notified the user by displaying a dialogue box. The dialogue box contained both captured CTDI	PASS

Requirement	Expected outcome	Scanners used for testing	Observed outcome	Test result
	applied. The threshold value is configurable by the user in a text file.		value as well as the threshold value applied. The threshold value is configurable by the user in a text file.	
SRS.001 Notification during **Pediatric Head** exam	The software captures the CTDI value for **Pediatric Head** and compares it to AAPM Dose Check Guidelines suggested threshold value (Default Value). If the value exceeds the threshold value, the software notifies the user by displaying a dialogue box. The dialogue box contains both captured CTDI value as well as the threshold value applied. The threshold value is configurable by the user in a text file.	GE Light Speed 32; Siemens Sensation 16; Philips Brilliance 64; Toshiba Aquilion 64;	The software captured the CTDI value for **Pediatric Head** and compared it to AAPM Dose Check Guidelines suggested threshold value (Default Value). If the value exceeded the threshold value, the software notified the user by displaying a dialogue box. The dialogue box contained both captured CTDI value as well as the threshold value applied. The threshold value is configurable by the user in a text file.	PASS
SRS.001 Notification during **Pediatric Body** exam	The software captures the CTDI value for **Pediatric Body** and compares it to AAPM Dose Check Guidelines suggested threshold value (Default Value). If the value exceeds the threshold value, the software notifies the user by displaying a dialogue box. The dialogue box contains both captured CTDI value as well as the	GE Light Speed 32; Siemens Sensation 16; Philips Brilliance 64; Toshiba Aquilion 64;	The software captured the CTDI value for **Pediatric Body** and compared it to AAPM Dose Check Guidelines suggested threshold value (Default Value). If the value exceeded the threshold value, the software notified the user by displaying a dialogue box. The dialogue box contained both	

Requirement	Expected outcome	Scanners used for testing	Observed outcome	Test result
	threshold value applied. The threshold value is configurable by the user in a text file.		captured CTDI value as well as the threshold value applied. The threshold value is configurable by the user in a text file.	
SRS.001 Notification during **Perfusion** exam	The software captures the CTDI value for **Perfusion** and compares it to AAPM Dose Check Guidelines suggested threshold value (Default Value). If the value exceeds the threshold value, the software notifies the user by displaying a dialogue box. The dialogue box contains both captured CTDI value as well as the threshold value applied. The threshold value is configurable by the user in a text file.	GE Light Speed 32; Siemens Sensation 16; Philips Brilliance 64; Toshiba Aquilion 64;	The software captured the CTDI value for **Perfusion** and compared it to AAPM Dose Check Guidelines suggested threshold value (Default Value). If the value exceeded the threshold value, the software notified the user by displaying a dialogue box. The dialogue box contained both captured CTDI value as well as the threshold value applied. The threshold value is configurable by the user in a text file.	
SRS.002 Alert if total CTDI exceeds threshold	The software calculates total CTDI value from each series and compares the accumulated value to AAPM Dose Check Guidelines suggested threshold value (Default Value). If the accumulated value exceeds the threshold value, the software alerts the user by displaying a dialogue box. The dialogue box	GE Light Speed 32; Siemens Sensation 16; Philips Brilliance 64; Toshiba Aquilion 64;	The software calculated total CTDI value from each series and compared the accumulated value to AAPM Dose Check Guidelines suggested threshold value (Default Value). If the accumulated value exceeded the threshold value, the software alerted the	PASS

Requirement	Expected outcome	Scanners used for testing	Observed outcome	Test result
	contains both accumulated CTDI value as well as the threshold value applied. The threshold value is configurable by the user in a text file.		user by displaying a dialogue box. The dialogue box contained both accumulated CTDI value as well as the threshold value applied. The threshold value is configurable by the user in a text file.	
SRS.003 Disable system during alert	Software shall use relay hardware to disable system from scanning when alert occurs	GE Light Speed 32; Siemens Sensation 16; Philips Brilliance 64; Toshiba Aquilion 64;	Software used relay hardware to disable system from scanning when alert occurred.	PASS
SRS.004 Record and Report	Software shall record and report CTDI and exam information.	GE Light Speed 32; Siemens Sensation 16; Philips Brilliance 64; Toshiba Aquilion 64;	Software recorded and reported CTDI and exam information.	PASS

8. Safety and Effectiveness:
Z-DOSE29 CT Dose Check system has similar indications for use as predicate device. The main difference is that the predicate devices employ either same CT host computer or a separate computer, that receive video signal from CT host screen for notifications, while Z-DOSE29 uses a remote computer on the same LAN as CT host computer for notifications and alerts. Risk analysis was performed to include design requirements and mitigations which prevent all known possible interferences in the normal operation of the host CT. Performance testing, along with verification and validation activities demonstrate that Z-DOSE29 is as safe and effective as predicate device.

9. Conclusion:
Z-DOSE29 is a CT Dose Check system which has similar indications for use as the predicate devices. Performance testing, verification and validation demonstrate that Z-DOSE29 is as safe and effective as the predicate devices.