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

December 15, 2016

Zetta Medical Technologies, LLC.
% Mr. Main Ghazal
President
1313 Ensell Road
LAKE ZURICH IL 60047

Re: K160852
Trade/Device Name: Zia™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 4, 2016
Received: November 4, 2016

Dear Mr. 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 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)*
K160852

Device Name
Zia™

Indications for Use *(Describe)*
Zia™ Image Enhancement System is an image processing software that can be used for reducing noise in CT images. Enhanced images will be uploaded back to host/PACS systems and exist in conjunction to the original images. Zia™ is not intended for mammography applications. The device processing is not effective for lesion, mass, or abnormalities of sizes less than 2mm.

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.

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirement of Titles 21 CFR §807.87 and 807.92.

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: November 2nd 2016

2. **Identification of the Device:**
   Trade Name: Zia™
   Common Name: Image Enhancement System
   Classification Name: Image Processing System, Radiological (21 CFR, 892.2050, LLZ)
   Regulatory Description: Picture Archiving and Communications System

3. **Predicate Device:**
   Context Vision Sharp View Image Enhancement System, K024028

4. **Indications for Use:**
   Zia™ Image Enhancement System is an image processing software that can be used for reducing noise in CT images. Enhanced images will be uploaded back to host/PACS systems and exist in conjunction to the original images. Zia™ is not intended for mammography applications. The device processing is not effective for lesion, mass, or abnormalities of sizes less than 2mm.

5. **Device Description:**
   Zia™ Image Enhancement System is an image processing software that can be used for reducing noise in CT images. Zia™ image enhancement software is based on a core noise reduction algorithm that reduces noise in flat regions via a regularization process while keeping the edges via data fidelity constrains. The software, which is installed on a remote computer, receives DICOM images from CT host computer (Zia DICOM node needs to be configured on the scanner), automatically processes the received images and uploads the post processed images back on to the host computer and/or other PACS systems. Enhanced images exist in conjunction to the original images.

6. **Substantial Equivalence Table**
   The subject device Zia™ is substantially equivalent to the predicate device, Sharp View Image Enhancement System, which is also used for image enhancement. The main difference is that Sharp View Image Enhancement System is multimodality image transfer/storage/enhancement system where as Zia (as of 10/27/2016) is strictly a CT

image enhancement system. Detailed differences between Zia and Sharp view systems are listed in Table-1.

Table -1: Zia vs Sharp View Image Enhancement System

Characteristics	Zia™	Sharp View Image Enhancement System
Indications for Use	Zia™ Image Enhancement System is an image processing software that can be used for reducing noise in CT images. Enhanced images will be uploaded back to host/PACS systems and exist in conjunction to the original images. Zia™ is not intended for mammography applications. The device processing is not effective for lesion, mass, or abnormalities of sizes less than 2mm.	The Image Enhancement System is intended for use by a qualified/trained technologist for transfer, storage, enhancement and viewing of multi-modality images.
Computer	PC or PC Compatible	PC compatible
Operating System	Windows 7	Windows 98, NT 4.0, 2000 and XP
Storage	Is not a primary image storage system. However, processed images are achieved on local hard drive	Hard disk or any compatible PC method: Optical, CDROM, Tape
Image Processing Hardware	CUDA supported graphics card or Equivalent	Javelin (PCI-bus) or Similar
Software core	Zia™ Image Enhancement Software (Zetta's own trademark)	GOP® Enhancement software (The GOP trademark is the property of Context Vision)
Image Input	DICOM	DICOM
Image output	DICOM	DICOM

7. Performance Testing:

Zia™ has been designed, verified and validated in compliance with FDA 21 CFR Part 820 requirements. The device has been validated through the use of ACR CT PHANTOM (Model 464) on a GE BrightSpeed 4-Slice, Siemens Sensation 16-Slice and Philips Brilliance 64-Slice scanners. Original images were acquired using a Head 120KV, Head 80KV, and Body 120KV protocols respectively. For each protocol, three mAs were selected in the range of 150-350mAs (150mAs, 250mAs, 350mAs), and three slice thickness were

selected in the range of 1.25-5mm (1.25mm, 2.5mm, 5mm). All original images were reconstructed using filtered back projection, standard kernel, and matrix size of 512x512. A total of 81 datasets were processed and analyzed including noise, CT# (signal), low contrast resolution and high contrast resolution. CT# was measured as an average of pixel values of each ROI encompassing the four inserts (Acrylic, Bone, Polyethylene and Air) in the CT# module. Noise was measured as standard deviation of pixel values of an ROI placed at the center of the noise module as well as the four ROIs encompassing the four inserts. The results demonstrated that the system meets all defined specifications. Table-2 below summarizes the performance test results. A noise reduction of at-least 10% while maintaining CT# accuracy within +/-1HU indicates that the device is able to increase signal to noise ratio in the processed images.

Table -2: Zia Performance Test Results Summary

Protocol parameters	Expected outcome	Scanners used for testing	Observed outcome	Test result
120kV, Head, mAs in range of 150-350, slice thickness in range of 1.25-5mm	Reduces noise in the processed images by at least 10%; keeps CT # (signal) accuracy within +/-1.0HU and maintains (preserves) high and low contrast resolutions.	GE BrightSpeed 4; Siemens Sensation 16; Philips Brilliance 64	Reduced noise in the processed images by at least 10%; kept CT # (signal) accuracy within +/-1.0HU and maintained (preserved) high and low contrast resolutions.	PASS
80kV, Head, mAs in range of 150-350, slice thickness in range of 1.25-5mm	Reduces noise in the processed images by at least 10%; keeps CT # (signal) accuracy within +/-1.0HU and maintains (preserves) high and low contrast resolutions.	GE BrightSpeed 4; Siemens Sensation 16; Philips Brilliance 64	Reduced noise in the processed images by at least 10%; kept CT # (signal) accuracy within +/-1.0HU and maintained (preserved) high and low contrast resolutions.	PASS
120kV, Body, mAs in range	Reduces noise in the	GE BrightSpeed 4;	Reduced noise in the	PASS

of 150-350, slice thickness in range of 1.25-5mm	processed images by at least 10%; keeps CT # (signal) accuracy within +/- 1.0HU and maintains (preserves) high and low contrast resolutions.	Siemens Sensation 16; Philips Brilliance 64	processed images by at least 10%; kept CT # (signal) accuracy within +/- 1.0HU and maintained (preserved) high and low contrast resolutions.	

8. Safety and Effectiveness:

Based on the software test results and the information supplied in this 510(k), we conclude that this device is safe, effective, and substantially equivalent to the predicate devices.

9. Conclusion:

Zia™ is an image enhancement software which has similar indications for use as predicate device. The main difference is that the predicate device is a multimodality image transfer/storage/enhancement system where as Zia (as of 10/27/2016) is strictly a CT image enhancement system. Performance testing, along with verification and validation activities demonstrate that Zia™ is as safe and effective as predicate device.