April 24, 2018

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

Re: K172768
Trade/Device Name: ZOOM
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: March 14, 2018
Received: March 23, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172768

Device Name
ZOOM

Indications for Use *(Describe)*
ZOOM Image Enhancement System is an image processing software that can be used for image enhancement in MRI images. Enhanced images will be sent to PACS server and exist in conjunction to the original images.

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.

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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: March 14th 2018

2. **Identification of the Device:**
   Trade Name: ZOOM
   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:**
   ZOOM Image Enhancement System is an image processing software that can be used for image enhancement in MRI images. Enhanced images will be sent to PACS server and exist in conjunction to the original images.

5. **Device Description:**
   ZOOM Image Enhancement System is an image processing software that can be used for image enhancement in MRI images. ZOOM image enhancement software implements a noise reduction algorithm using wavelets and image guided filtering. Original images are decomposed into different wavelet sub bands and noise in each band is soft threshold. De-noised images are reconstructed from soft-thresholded images using inverse wavelet transform. The software, which is installed on a remote computer, receives DICOM images from MRI host computer, automatically processes the received images and sends the enhanced images to a PACS server. Enhanced images exist in conjunction to the original images.

6. **Substantial Equivalence Table**

The subject device ZOOM is substantially equivalent to the predicate device, Sharp View Image Enhancement System. The main difference is that Sharp View Image Enhancement System is a multimodality image transfer/storage/enhancement system where as ZOOM (as of 7/27/2017) is strictly an MRI image enhancement software. Detailed differences between ZOOM and Sharp view systems are listed in Table-1.

Table -1: ZOOM vs Sharp View Image Enhancement System

Characteristics	ZOOM	Sharp View Image Enhancement System
Indications for Use	ZOOM Image Enhancement System is an image processing software that can be used for image enhancement in MRI images. Enhanced images will be sent to PACS server and exist in conjunction to the original images.	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 archived on local hard drive	Hard disk or any compatible PC method: Optical, CDROM, Tape
Image Processing Hardware	Intel i3 processor, 4GB RAM, 500GB Hard drive	Javelin (PCI-bus) or Similar
Software core	ZOOM 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:**

ZOOM 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 MRI PHANTOM. A total of 64 data sets were acquired using spin echo, fast spin echo and gradient echo based sequences from the following systems: GE 1.5T Excite, Siemens Avanto 1.5T, Philips Intera 1.5T and Toshiba Titan 1.5T. Parameters (slice thickness, field of view, matrix dimensions and number of averages) that effect the signal to noise ratio (SNR) were varied while acquiring the 64 data sets. These data sets were processed using ZOOM software for image enhancement and results are compared between original and processed images. Performance test results indicate that the ZOOM software improves SNR by at least 10% without degrading high and low contrast resolutions.

Table - 2: High level performance test results

Requirement specification	Verified on systems	Result
For **spin echo large phantom protocol in ACR quality control 2015**, the software shall increase SNR by at-least 10% in slice 7 ACR data without compromising high contrast resolution in slice 1 and low contrast resolution in slice 11	• GE 1.5T Excite • Siemens Avanto 1.5T • Philips Intera 1.5T • Toshiba Titan 1.5T	Pass
For **fast spin echo sequences with slice thickness in the range 2-5mm and in-plane resolution in the range 0.6-1.4 mm**, the software shall increase SNR by at-least 10% in slice 7 ACR data without compromising high contrast resolution in slice 1 and low contrast resolution in slice 11	• GE 1.5T Excite • Siemens Avanto 1.5T • Philips Intera 1.5T • Toshiba Titan 1.5T	Pass
For **gradient echo sequences with slice thickness in the range 2-5mm and in-plane resolution in the range 0.6-1.4 mm**, the software shall increase SNR by at-least 10% in slice 7 ACR data without compromising high contrast resolution in slice 1 and low contrast resolution in slice 11	• GE 1.5T Excite • Siemens Avanto 1.5T • Philips Intera 1.5T • Toshiba Titan 1.5T	Pass
For **spin echo small phantom protocol in ACR quality control 2015**, the software shall increase SNR by at-least 10% in slice 7 ACR data without compromising high	• GE 1.5T Excite • Siemens Avanto 1.5T • Philips Intera 1.5T • Toshiba Titan 1.5T	Pass

contrast resolution in slice 1 and low contrast resolution in slice 11		

8. **Safety and Effectiveness:**
   Based on the ZOOM software performance test results and incorporated risk minimization methods in design, Zetta Medical Technologies concludes that this device is substantially equivalent to the predicate device.

9. **Conclusion:**
   ZOOM 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 ZOOM (as of 7/27/2017) is strictly an MRI image enhancement system. Performance test results and incorporated risk minimization methods demonstrate that ZOOM is as safe and effective as predicate device.