December 22, 2020

AI Metrics, LLC
% Yujan Shrestha, M.D.
CTO
Innolitics, LLC
1101 West 34th Street #550
AUSTIN TX 78705

Re: K202229
Trade/Device Name: AI Metrics
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: November 11, 2020
Received: November 13, 2020

Dear Dr. Shrestha:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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)*
K202229

Device Name
AI Metrics

Indications for Use *(Describe)*
AI Metrics is a software solution intended to be used for viewing, manipulation, communication, storage, annotation, analysis, and comparison of medical images from multiple imaging modalities and/or multiple time points. The application supports images and anatomical datasets, such as CT and MR. AI Metrics is a software only medical device to be deployed via internet software download and installed by trained AI Metrics technicians.

AI Metrics enables visualization of information that would otherwise have to be visually compared disjointedly. AI Metrics provides analytical and workflow automation tools to help the user assess and document the extent of a disease and/or the response to therapy in accordance with user selected standards and assess changes in imaging findings over multiple time-points. AI Metrics supports the interpretation and evaluation of examinations and follow up documentation of findings within healthcare institutions, for example, in Radiology, Oncology, and other Medical Imaging environments.

The product is intended to be used as a workflow automation tool by trained medical professionals. It is intended to provide image and related information that is interpreted by a trained professional but does not directly generate any diagnosis or potential findings.

Note: The medical professional retains the ultimate responsibility for making the pertinent diagnosis based on their standard practices. AI Metrics is a complement to these standard procedures. AI Metrics is not to be used in mammography.

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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205-573-3332
www.aimetrics.com

5. 510(k) Summary

K202229

In accordance with 21 CFR 807.92, the following summary of information in the 510(k) submission is provided.

5.1 Identification of the Submitter

Submitter:	AI Metrics LLC 432 Renaissance Dr. Hoover, AL 35226 Phone: 205-573-3332 Website: www.aimetrics.com
Primary Contact:	Dr. Andrew Smith, Founder Email: andrew@aimetrics.com Phone: (769) 610-6235
Company Contact:	Bob Jacobus, COO Email: bob@aimetrics.com Phone: (205) 639-8618
Date Prepared:	September 9, 2020

5.2 Identification of the product

Trade Name:	AI Metrics
Common Name:	Image Processing Software
Classification:	Picture Archiving and Communications System per 21 CFR 892.2050
Review Panel:	Radiology
Device Class:	Class II
Product Code:	LLZ

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5.3 Predicate Device to which Equivalence is claimed

Device Name:	mint Lesion
Manufacturer:	Mint Medical GmbH Germany
510(k) Number:	K142647
Product Code:	LLZ
Classification:	Picture Archiving and Communications System per 21 CFR 892.2050

5.4 Device Description

AI Metrics is a software based Picture Archiving and Communication System (PACS) used with general purpose computing hardware for the display and visualization of medical image data. It runs on either a native or a virtualized Linux platform. The application supports images and anatomical datasets, such as CT and MR.

AI Metrics is designed as a workflow automation application with analytical tools to help the user assess, categorize and document the extent of a disease and/or tumor response to therapy in accordance with user selected standards (e.g. RECIST 1.1) and assess changes in imaging findings over multiple time-points.

AI Metrics supports the interpretation and evaluation of examinations and follow up documentation of findings within healthcare institutions, for example, in Radiology, Oncology, and other Medical Imaging environments.

AI Metrics functionality provides for communication, storage, processing, rendering, and display of DICOM compliant image data derived from various sources including anatomical datasets (e.g. CT, MRI), navigation through images, selection of regions of interest, generation of information from those regions, evaluation in accordance with user selected standards, and generation of a structured report.

The user controls these functions with a system of interactive menus and semi-automated or manual workflow automation tools, including:

- Manual annotation tools for users to select regions of interest (ROIs),
- Semi-automatic lesion segmentation suggestions for user-selected ROIs,
- Automatic measurement and display of long and short axis of segmented lesions,
- Automatic tabulation and summation of measurements,

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- Semi-automatic lesion labelling suggestions for anatomical location (organ, body region, and laterality),
- Automatic calculation of quantitative and qualitative metrics using annotation data in accordance with the selected criteria, and
- Automatic generation of a structured report that includes the annotation data and calculated quantitative and qualitative metrics presented in a graph, table, key images, and structured text report.

AI Metrics software has been extensively tested on Linux systems by members of the development and quality control teams. A hazard analysis has been conducted and all risks have been determined to be acceptable. The release candidate version of the software passed all tests considered critical in terms of patient safety and demonstrated an overall acceptable performance.

5.5 Intended Use

AI Metrics is a software solution intended to be used for viewing, manipulation, communication, storage, annotation, analysis, and comparison of medical images from multiple imaging modalities and/or multiple time points. The application supports images and anatomical datasets, such as CT and MR. AI Metrics is a software only medical device to be deployed via internet software download and installed by trained AI Metrics technicians.

AI Metrics enables visualization of information that would otherwise have to be visually compared disjointedly. AI Metrics provides analytical and workflow automation tools to help the user assess and document the extent of a disease and/or the response to therapy in accordance with user selected standards and assess changes in imaging findings over multiple time-points. AI Metrics supports the interpretation and evaluation of examinations and follow up documentation of findings within healthcare institutions, for example, in Radiology, Oncology, and other Medical Imaging environments.

The product is intended to be used as a workflow automation tool by trained medical professionals. It is intended to provide image and related information that is interpreted by a trained professional but does not directly generate any diagnosis or potential findings.

Note: The medical professional retains the ultimate responsibility for making the pertinent diagnosis based on their standard practices. AI Metrics is a complement to these standard procedures. AI Metrics is not to be used in mammography.

AI METRICS

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5.6 Substantial Equivalence Comparison to the Predicate Device

The following tables summarize the intended use and technological characteristics of AI Metrics and the predicate device mint Lesion.

Intended Use	Subject (AI Metrics)	Predicate (K142647)
Thin client medical image viewer.	Yes.	Yes.
Software only medical device deployed within a customer's IT infrastructure or on virtualized server technology.	Yes.	Yes.
Application supports anatomical datasets, such as CT and MR.	Yes.	Yes. Also supports functional datasets.
To be used for viewing, manipulation, communication, storage, 3D-visualization and comparison of medical images from multiple imaging modalities and/or multiple time points.	Yes.	Yes.
Provides tools to help the user assess and document the extent of a disease and/or the response to therapy in accordance with user selected standards.	Yes.	Yes.
Supports the interpretation and evaluation of examinations and follow up documentation of findings within healthcare institutions, for example, in Radiology, Oncology, and other Medical Imaging environments.	Yes.	Yes. Includes Nuclear Medicine environments.
The medical professional retains the ultimate responsibility for making the pertinent diagnosis based on their standard practices. The software is a complement to these standard procedures.	Yes.	Yes.
Not be used in mammography.	Yes.	Yes.

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Technological Characteristic	Subject (AI Metrics)	Mint Lesion (K142647)
Design		
Software-based Picture Archiving and Communication System (PACS) used with general purpose computing hardware.	Yes.	Yes.
Operating system / Run environment	Windows 64 / native or virtualized Microsoft Windows platform.	Linux / native or virtualized Linux platform.
Software delivery method	CD ROM/DVD or internet.	Internet software download.
Features and Functionality		
Image navigation tools (pan, zoom, scroll, window/level)	Yes.	Yes.
Measurement tools (linear, ROI, HU)	Yes.	Yes.
Automatic long and short axis calculations	Yes.	Yes.
User controls functions with a system of interactive menus and tools	Yes.	Yes.
Semi-automatic lesion segmentation tools	Yes.	Yes.
Anatomical location labelling tools	Yes.	Yes.
Display output of measurements and anatomical location information	Yes.	Yes.
Tabulation and summation of measurements, lesion categorization and standard evaluation in accordance with selected criteria	Yes.	Yes.

Longitudinal lesion analysis	Yes.	Yes.
Image co-registration for viewing images from different time points	Yes.	Yes.
Report generation	Yes.	Yes.

AI Metrics has the same intended use as the predicate device. AI Metrics does not support functional datasets such as PET. In addition to the shared indications for use in radiology and oncology, the predicate device also includes indications for use in nuclear medicine environments. AI Metrics does not support functional datasets and therefore does not have indications for use in nuclear medicine environments. We believe these differences do not raise different questions of safety and effectiveness.

AI Metrics and the predicate device are substantially equivalent in the categories of technical characteristics and features. We believe the differences in operating systems and software delivery methods do not raise different questions of safety and effectiveness. The software delivery method itself will undergo verification and validation activities to ensure it does not adversely affect the safety and effectiveness of the device.

5.7 Summary of Studies

AI Metrics has successfully undergone extensive verification and validation testing to ensure that all requirements for the software were met per FDA Guidance. The software design and development process followed the ISO 62304 standard. The software was tested against the established Software Design Specifications and passed all required tests. A Risk Management Report was completed which identified and verified the mitigation of all required hazards in compliance with ISO 14971 standard. Quality management systems follow the ISO 13485 standard. These results provide objective evidence that the outputs of the software design activity meet all of the specified requirements for that activity.

5.9 Conclusion

AI Metrics has the same intended use and technological characteristics as the predicate device. Any differences between AI Metrics and the predicate device do not raise different questions of safety and effectiveness. The result of all testing conducted was found acceptable to support the claim of substantial equivalence.