December 27, 2017

Microsoft Corp.
% Donna-Bea Tillman, Ph.D.
Senior Consultant
Biologics Consulting Group, Inc.
1555 King Street, Suite 300
ALEXANDRIA VA 22314

Re: K173420
Trade/Device Name: Radiomics App v1.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 31, 2017
Received: November 1, 2017

Dear Dr. Tillman:

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 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)*
K173420

Device Name
Radiomics App v1.0

Indications for Use *(Describe)*
Microsoft Radiomics App v1.0 is a software-only medical device intended for use by trained radiation oncologists, dosimetrists and physicists to derive optimal organ and tumor contours for input to radiation treatment planning. Supported image modalities are Computed Tomography and Magnetic Resonance. Radiomics App assists in the following scenarios:

- Load, save and display of medical images and contours for treatment evaluation and treatment planning.
- Creation, transformation, and modification of contours for applications including, but not limited to: transferring contours to radiotherapy treatment planning systems, aiding adaptive therapy, and archiving contours for patient follow-up.
- Localization and definition of both solid tumors and healthy anatomical structures.
- Fusion display of compatible images for treatment planning.
- Three-dimensional rendering of medical images and the segmented contours.

Images reviewed using the Radiomics App software should not be used for primary image interpretations. Radiomics App is not for use with digital 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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510(K) SUMMARY

1. SUBMITTER

Submitter:	Microsoft Corp 1 Microsoft Way Redmond, WA 98052 Phone: 425-538-9419
Contact Person:	Ivan Tarapov Ivan.Tarapov@microsoft.com
Submission Correspondent:	Donna-Bea Tillman, Ph.D, MPA Biologics Consulting Group, Inc. 1555 King Street, Suite 300 Alexandria, VA 22314 Phone: 410-531-6542 dtillman@biologicsconsulting.com
Date Prepared:	October 31, 2017

2. DEVICE

Name of Device:	Radiomics App v1.0
Common or Usual Name:	Radiological Image Processing System
Classification Name:	Picture Archiving and Communications System 21 CFR 892.2050
Regulatory Class:	Class II
Product Code:	LLZ

3. PREDICATE DEVICE

Predicate Device Name:	MIM 5.2 (BRACHY)
Manufacturer:	MIM Software Inc.
510(k) Number:	K103576
Reference Devices:	No reference devices were used in this submission.

4. DEVICE DESCRIPTION

Microsoft Radiomics App v1.0 is a software-only medical device intended for use by trained radiation oncologists, dosimetrists and medical physicists for radiation treatment planning.

Radiomics App stems from more than eight years of research in computerized medical image analysis, computer vision and machine learning. It applies well tested, state-of-the-art algorithms for the assisted delineation of anatomical structures of interest in three-dimensional, clinical radiological scans.

Radiomics App works on computed tomography (CT) and magnetic resonance (MR) scans, and is designed to contour/delineate both healthy anatomical structures as well as lesions such as solid tumors.

Radiomics App integrates into the clinical data network of radiation therapy treatment centers, receiving data from imaging devices such as CT and MR scanners. The purpose of the tool is to assist the expert user in producing segmentations (three-dimensional contours) of anatomical structures, for both solid tumors and healthy tissue structures. The following segmentation tools are provided:

- **Assisted Contouring.** This module allows for the manual, user-guided segmentation of structures of interest in both CT and MR images.
- **Machine-learning based contouring**. This module uses machine learning algorithms (ML) to provide an initial segmentation of certain structures of interest automatically. The user has the option to accept this initial segmentation or edit and refine it.
- **Contour refinement.** This module allows the user to edit and improve segmentations created by either the machine learning or the assisted contouring algorithms.

These segmentations are then exported back into the clinical data network, and subsequently utilized in a radiotherapy treatment planning system to generate a treatment plan for a patient.

5. INDICATION FOR USE

Microsoft Radiomics App v1.0 is a software-only medical device intended for use by trained radiation oncologists, dosimetrists and physicists to derive optimal organ and tumor contours for input to radiation treatment planning. Supported image modalities are Computed Tomography and Magnetic Resonance. Radiomics App assists in the following scenarios:

- Load, save and display of medical images and contours for treatment evaluation and treatment planning.
- Creation, transformation, and modification of contours for applications including, but not limited to: transferring contours to radiotherapy treatment planning systems, aiding adaptive therapy, and archiving contours for patient follow-up.
- Localization and definition of both solid tumors and healthy anatomical structures.
- Fusion display of compatible images for treatment planning.
- Three-dimensional rendering of medical images and the segmented contours.

Images reviewed using the Radiomics App software should not be used for primary image interpretations.

Radiomics App is not for use with digital mammography.

Comparison of Indications for Use

Both devices are only intended for use by trained medical professionals. As noted below, both devices are intended for use during radiation therapy planning. The subject device supports a subset of the image modalities supported by the predicate device. Both devices accept DICOM images generated elsewhere as inputs. Both devices provide the user with tools to contour medical images for use in radiation therapy planning and patient follow-up. Both devices can be used to localize and define normal tissues as well as solid tumors. Both devices support the fusion of different image modalities. Both devices provide three-dimensional image rendering. The subject device is not intended for primary image interpretation or for use with digital mammography. This is a subset of the indications of the predicate device.

The minor differences in indications of use between the subject Radiomics App and the predicate MIM software do not constitute a different intended use.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The table below provides a side-by-same comparison of the technological characteristics of the proposed Radiomics App and the predicate MIM Software.

	Proposed Device	**Predicate Device**
510(k) Number	TBD	K103576
Applicant	Microsoft	MIM Software
Device Name	Radiomics App	MIM 5.2
Classification Regulation	892.2050 – Picture Archiving and Communication System	892.2050 – Picture Archiving and Communication System
Product Code	LLZ	LLZ
Indications for Use	Microsoft Radiomics Advanced Image Contouring v1.0 (Radiomics App) is a software-only medical device intended for use by trained radiation oncologists, dosimetrists and physicists to derive optimal organ and tumor contours for input to radiation treatment planning. Supported image modalities are Computed Tomography and Magnetic Resonance. Radiomics App assists in the following scenarios: Load, save and display of medical images and contours for treatment evaluation and treatment planning. Creation, transformation, and modification of contours for applications including, but not limited to: transferring contours to radiotherapy treatment planning systems, aiding adaptive therapy, and archiving contours for patient follow-up. Localization and definition of both solid tumors and healthy anatomical structures. Fusion display of compatible images for treatment planning. Three-dimensional rendering of medical images and the segmented contours. Images reviewed using the Radiomics	MIM 5.2 software is used by trained medical professionals as a tool to aid in evaluation and information management of digital medical images. The medical image modalities include, but are not limited to, CT, MRI, CR, DX, MG, US, SPECT, PET and XA as supported by ACRINEMA DICOM 3.0. MIM *5.2* assists in the following indications Receive, transmit, store, retrieve, display, print, and process medical images and DICOM objects. Create, display and print reports from medical images. Registration, fusion display, and review of medical images for diagnosis, treatment evaluation, and treatment planning. Evaluation of cardiac left ventricular function and perfusion, including left ventricular end-diastolic volume, end-systolic volume, and ejection fraction. Localization and definition of objects such as tumors and normal tissues in medical images. Creation, transformation, and modification of contours for applications including, but not limited to, quantitative analysis, aiding adaptive therapy, transferring contours to radiation therapy treatment planning systems, and archiving contours for patient follow-up

	Proposed Device	Predicate Device
	App software should not be used for primary image interpretations. Radiomics App is not for use with digital mammography.	and management. Quantitative and statistical analysis of PET/SPECT brain scans by comparing to other registered PET/SPECT brain scans. Planning and evaluation of permanent implant brachytherapy procedures. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Images that are printed to film must be printed using a FDA-approved printer for the diagnosis of digital mammography images. Mammographic images must be viewed on a display system that has been cleared by the FDA for the diagnosis of digital mammography images. The software is not to be used for mammography CAD.
Intended users	Healthcare providers	Healthcare providers
Contouring modes	Assisted and automatic	Assisted and automatic
Types of tissue contoured	Tumors and normal tissues	Tumors and normal tissues
Measurements	2D distance measurement, average tissue density within a region (for CT), segmentation volume	2D distance measurement, segmentation volume, average tissue density within a region (for CT)
Image Fusion	Fuse only two 3D images, CT and MR	Fuse medical images from multiple modalities
3D image rendering	Yes	Yes
Cardiac applications	No	Yes
Dose visualization and manipulation	No	Yes
Image modalities	CT and MR	CT, MRI, CR, DX, MG, US, SPECT, PET and XA
Platform	Stand-alone package which operates on Microsoft Windows operating systems only.	Stand-alone package which operates on both Windows and Mac computer systems.

7. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility

The subject device is a software-only device. There are no direct or indirect patient-contacting components of the subject device. Therefore, patient contact information is not needed for this device.

Electrical Safety and electromagnetic compatibility (EMC)

Not applicable. The subject device is a software-only device. It contains no electric components, generates no electrical emissions, and uses no electrical energy of any type.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a moderate level of concern.

Verification Testing

Two different types of verification testing were conducted to verify the software requirements: Manual and Automated. All tests passed, demonstrating that the software performance is in accordance with the stated software requirements.

Validation Testing

Validation testing of the following functions of the Radiomics App demonstrated that the software meets user needs and intended uses and to support substantial equivalence:

- Measurements - Validation Test
- Volumetric Rendering – Validation Test
- Multi-Planar Reconstruction – Validation Test
- Assisted Contouring – Validation Test
- Automatic Contouring – Validation Test

Animal Study

Not applicable. Animal studies are not necessary to establish the substantial equivalence of this device.

Clinical Study

Not applicable. Clinical studies are not necessary to establish the substantial equivalence of this device.

8. CONCLUSIONS

The minor differences in indications of use between the subject Radiomics App and the predicate MIM software do not constitute a different intended use. The technological characteristics of the Radiomics App are similar to those of the MIM Software, with the biggest differences being that the Radiomics App offers a subset of the features provided by the MIM software. Results of software verification and validation testing demonstrate that the Radiomics App performs in accordance with specifications and that the performance is comparable to that of the predicate device. Therefore, the Radiomics App can be found to be substantially equivalent to the predicate MIM Software.