Medipixel, Inc.
℅ Hye-ri Choi
RA Manager
Dooam Building 7F, 61, Yangwha-ro, Mapo-gu
Seoul, 04037
REPUBLIC OF KOREA

Re: K222036 March 22, 2023
Trade/Device Name: MPXA-2000
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: February 21, 2023
Received: February 23, 2023

Dear Hye-ri Choi:

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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222036

Device Name
MPXA-2000

Indications for Use *(Describe)*

MPXA-2000 is indicated for use in clinical settings where validated and reproducible quantified results are needed to support the calculations in X-ray angiographic images of the coronary arteries, for use on individual patients with coronary artery disease (CAD). MPXA-2000 is indicated for use in adult patient only.
When the quantified results provided by MPXA-2000 are used in a clinical setting on X-ray images of an individual patient, they can be used to support the clinical decisions making for the diagnosis of the patient or the evaluation of the treatment applied. In this case, the results are explicitly not to be regarded as the sole, irrefutable basis for clinical diagnosis, and they are only intended for use by the responsible clinicians.

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

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

1) DATE PREPARED [21 CFR 807.92(a)(1)]

March 15, 2023

2) SUBMITTER'S INFORMATION [21 CFR 807.92(a)(1)]

510(k) Owner (Manufacturer)	Medipixel, Inc. Dooam Building 7F, 61, Yanghwa-ro, Mapo-gu, Seoul, Republic of Korea, 04037 Phone: +82-70-4699-0460 Fax: +82-50-7534-4375 E-mail: contact@medipixel.io
Correspondence Person	Seokjin Ham Quality Management Representative of Medipixel, Inc. Phone: +82-10-3664-3896 E-mail: harry.ham@medipixel.io Hye-Ri Choi RA Manager of Medipixel, Inc. Phone: +82-70-4699-0460 E-mail: contact@medipixel.io

3) SUBJECT DEVICE [21 CFR 807.92(a)(2)]

Proprietary name	Medipixel XA
Model Name	MPXA-2000
Common/Usual Name	Cardiovascular Image Analysis Software
Product Code	QIH
Regulation Number	21 CFR 892.2050
Classification Names	Automated Radiological Image Processing Software
Device Class	II
Classification Panel	Radiology

4) PREDICATE DEVICE [21 CFR 807.92(a)(3)]

The identified predicate devices within this submission are shown as follows:

Proprietary Name	QAngio XA (X-RAY VVA, K112807)
Common/Usual Name:	Radiological Image Processing Software
Product Code	LLZ

Regulation Number	21 CFR 892.2050
Classification Names	System, Image Processing, Radiological
Device Class	II
Classification Panel	Radiology

5) DEVICE DESCRIPTION [21 CFR 807.92(a)(4)]

MPXA-2000, the stand-alone application, is cardiovascular image analysis software for the viewing and quantification of X-ray angiographic images of the coronary arteries. Automatic vessel contour detection (i.e. vessel segmentation) forms the basis for the analyses. MPXA-2000 provides automatic analysis through segmentation of vessels and calculation of the segmented vessel's dimensions. MPXA-2000 is developed based on Deep-learning (Classification and Segmentation of vessels) and Computer vision algorithms (Measurements of vessels) to analyze the images and provide quantification of the vessels in real-time. It allows accurate and reproducible quantification of the coronary arteries from a set of those images in DICOM format.

MPXA-2000 is composed of the following key analysis workflow and functionalities:

- Image Uploading, Frame Selection
- Vessel Segmentation
- Classification of Vessel types
- ROIs (regions of Interest) Quantification
- Visualization & Export of the Analysis Results.

The analysis results are available on the screen and can be exported in PDF or Excel file format. MPXA-2000 has been validated for the images produced by FDA-approved X-ray angiography systems from Philips Medical Systems, Siemens Healthineers, GE Healthcare. The input data should be X-ray angiographic images that comply with the DICOM standard.

6) INTENDED FOR USE/INDICATIONS FOR USE [21 CFR 807.92(a)(5)]

Intended Use

MPXA-2000 is software intended to be used for performing calculations in X-ray angiographic images of the coronary arteries. These calculations are based on vessel contours which are automatically detected by the software and subsequently presented for review and manual editing.
The analysis results obtained with MPXA-2000 are intended for use by cardiologists and radiologists:
- to support clinical decisions concerning the coronary arteries.
- to support the evaluation of intervention or drug therapy applied for conditions of the coronary arteries.

Indications for Use

MPXA-2000 is indicated for use in clinical settings where validated and reproducible quantified results are needed to support the calculations in X-ray angiographic images of the coronary arteries, for use on individual patients with coronary artery disease (CAD). MPXA-2000 is indicated for use in adult patients only.
When the quantified results provided by MPXA-2000 are used in a clinical setting on X-ray images of an individual patient, they can be used to support the clinical decisions making for the diagnosis of the patient or

the evaluation of the treatment applied. In this case, the results are explicitly not to be regarded as the sole, irrefutable basis for clinical diagnosis, and they are only intended for use by the responsible clinicians.

7) TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE [21 CFR 807.92(a)(6)]

The comparison of the technological characteristics of the predicate and subject device is given in the table below.

General Information

Item	New device	Predicate Device
Device Name	MPXA-2000	QAngio XA (X-RAY VVA)
Manufacturer	Medipixel, Inc.	Medis Medical Imaging Systems, B.V.
510(k) Number	-	K112807
Product code	QIH	LLZ
Regulation No.	21 CFR 892.2050	21 CFR 892.2050
Class	II	II
Indications for Use	MPXA-2000 is indicated for use in clinical settings where validated and reproducible quantified results are needed to support the calculations in X-ray angiographic images of the coronary arteries, for use on individual patients with coronary artery disease (CAD). MPXA-2000 is indicated for use in adult patients only. When the quantified results provided by MPXA-2000 are used in a clinical setting on X-ray images of an individual patient, they can be used to support the clinical decisions making for the diagnosis of the patient or the evaluation of the treatment applied. In this case, the results are explicitly not to be regarded as the sole, irrefutable basis for clinical diagnosis, and they are only intended for use by the responsible clinicians.	X-RAY VVA is indicated for use in clinical settings where validated and reprodlucible quantified results are needed to support the calculations in X-ray angiographic images of the chambers of the and heart of blood vessels, for use on individual patients with cardiovascular disease. When the quantified results provided by X-RAY VVA are used in a clinical setting on X-ray images of an individual patient, they can be used to support the clinical decisions making for the diagnosis of the patient or the evaluation of the treatment applied. In this case, the results are explicitly not to be regarded as the sole, irrefutable basis for clinical diagnosis, and they are only intended for use by the responsible clinicians.
Patient Population	Patient with cardiovascular disease.	Patient with cardiovascular disease.
Intended Users	Cardiologists, Radiologists	Cardiologists, Radiologists

Software Version	1.0	7.3

Technological characteristics

Input data type		X-ray angiographic data in DICOM format (vendor-independent)	X-ray angiographic data in DICOM format (vendor-independent)
Manual editing of automatic results by user		Yes	Yes
Calibration		- Automatic calibration based on isocenter calibration factor in DICOM file - Other manual calibration options (catheter calibration)	- Automatic calibration based on isocenter calibration factor in DICOM file - Other manual calibration options (catheter, marker catheter, sphere, grid, circle manual and line calibration)
Automatic angiographic series loading into the software from the angiography equipment		Yes	No
Visualization/ Edit Tools		✓ Zooming, panning ✓ Editing vessel contours ✓ Angle, Length, Area, Text Annotation	✓ Zooming, panning ✓ Editing vessel contours
Quantitative Analysis	Automated 2D arterial contour segmentation	Yes	Yes
	Classification of vessel types	Yes LAD, LCX, and RCA	No
	Optional Stent analysis including stent edges	No	Yes
Analysis Results	Results for multiple lesions and additional user-defined ROI[a)]	Results for multiple lesions and additional user-defined ROI[a)]	Results for multiple lesions and additional user-defined ROI[a)]
	Vessel analysis	main and side branch	Straight (main), ostial, and bifurcation (side branch)
	Vessel quantifications	- % Diameter Stenosis - Minimum lumen diameter (MLD) - Proximal and distal diameters (at P- and D-marker positions) - ROI[a)] length - Reference Diameter	- % Diameter Stenosis - Minimum lumen diameter (MLD) - Proximal and distal diameters (at P- and D-marker positions) - Lesion length - Reference Diameter
	Stent related statistics	No	- Length of stent and stent

			edges - MLD and its position - In-stent Mean diameter
Ventricle analysis		No	Yes
Automatically load and visualize ECG data acquired from the DICOM file		Yes	No
Automatic EoD (End of Diastole) phase detection in DICOM file based on ECG.		Yes	No
Data Reporting		Patient and study details, calibration, annotation, measurement, and analysis details.	Patient and study details, calibration, annotation, measurement, and analysis details.
Export file formats		PDF, Excel	DICOM, BMP, JPEG, AVI and the raw file format

a) The term ROI (Region of Interest) refers to a narrowed area in a segmented blood vessel

MPXA-2000 has virtually the same intended use and indications for use as the predicate devices QAngio XA (K112807). Both devices are software intended to be used for the quantitative analysis in X-ray angiographic images. The qualified results provided by both devices can be used to support the clinical decisions making for the diagnosis of the patient or the evaluation of the treatment applied. The basic features as shown below in technological characteristics of both MPXA-2000 and the predicate device (QAngio XA) are the same:

- Input images provided in a DICOM format
- Automatic vessel segmentation (contour detection) of the coronary vessels
- Manual editing of the automated result by the user
- Quantification of coronary arteries based on the analysis of angiographic image
- Reporting of quantitative analysis results

The differences in technical characteristics between MPXA-2000 and the predicate QAngio XA are as follows:

- MPXA-2000 provides the automatic classification of vessel types such as LAD, LCX, and RCA. QAngio XA does not provide it.
- Both MPXA-2000 and the predicate device, QAngio XA, have the same feature to automatically detect the contour of coronary vessels. However, this feature differs slightly between the two products in terms of technical characteristics. The difference is that MPXA-2000 automatically finds the main and bifurcation vessels in the image, and also automatically detects their contours, but in QAngio XA, a user must designate the vessel to be segmented in advance.
- The predicate device, QAngio XA has the following additional features that MPXA-2000 does not provide.
  - Calculations in X-ray angiographic images of the left ventricle of the heart
  - Segmentation and quantification of the ostium part of vessels
  - Analysis of vessels treated with stents

Among the differences mentioned above, the features of the automatic vessel type classification and vessel segmentation that MPXA-2000 provides are based on Deep-learning algorithm. The Deep-learning algorithm used in MPXA-2000 was validated by the standalone performance test (Doc. No. TD-XA2-SPTR) using the method of comparing the analysis results obtained from MPXA-2000 with the ground truth annotated by experienced experts. The testing results are as follows:

- The vessel classification accuracy: 0.9934
- The vessel segmentation Dice similarity Coefficient (DSC): 0.9200(Pass criteria of > 0.8)

In addition to that, the results of ROI analysis in the standalone performance test show that the estimation of minimum luminal diameter by MPXA-2000, which is based upon this automatic segmentation feature, is comparable to the reported performance of the predicate device QAngio XA. (Doc. No. TD-XA2-SPTR)
All those results above demonstrate that those differences in technical characteristics do not raise any different questions of safety and effectiveness.

And the additional features above of the predicate device do not affect or alter the intended use and indication for use. Although MPXA-2000 does not have these features, it does not raise different questions of safety and effectiveness.

Furthermore, the safety and effectiveness of MPXA-2000 were evaluated and validated in accordance with software specifications and applicable performance standards through software V&V testing and standalone performance testing. The standalone performance test consists of 1) vessel segmentation assessment, 2) vessel classification assessment, and 3) ROI analysis assessment. The software validation activities were performed in accordance with IEC 62304: 2015 Medical device software – Software life cycle processes, in addition to the FDA Guidance documents, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and "Content of Premarket Submission for Management of Cybersecurity in Medical Devices."

In conclusion, MPXA-2000′s new features added to increase the convenience of use and functionality do not alter the intended use of the device to be used for performing calculations in X-ray angiographic images of the coronary arteries. And the new device does not raise different questions of safety and effectiveness.

8) Summary of Non-Clinical Testing Performed [21 CFR 807.92(b)(1)]

The product has been evaluated for software safety and performance and has been found to conform to applicable medical device safety standards and guidance documents.

MPXA-2000 complies with the following standards:
- IEC 62304 Edition 1.1 2015-06 Medical device software - Software life cycle processes

MPXA-2000 complies with the following guidance:
- General Principles of Software Validation (Jan 11, 2002)
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices: Guidance for Industry and FDA Staff (Nov 05, 2005)
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, (Oct 2, 2014)

Performance testing

MPXA-2000 was developed and tested in accordance with Medipixel' Design Control processes and has been subject to extensive safety and performance testing. Non-clinical verification and validation test results established that the device meets its design requirements and intended use. Specifically, software verification was conducted at unit (module) and system integration levels. Risk management analysis generated multiple risk mitigation measures and verification activities. A cybersecurity verification testing was conducted to demonstrate the integrity, confidentiality, and availability of MPXA-2000 through testing for identified vulnerabilities of product.

Stand-alone performance testing, a quantitative assessment of MPXA-2000's performance, was carried out by using 305 coronary angiograms collected from the US population. The angiograms for this testing were collected retrospectively from Philips Medical Systems Nederland B.V. under the data-sharing agreement. A

quantitative assessment of MPXA-2000's performance was carried out by using 305 coronary angiograms collected from the US population. Test datasets were strictly segregated from algorithm training datasets. Three features of MPXA-2000 were tested: vessel segmentation, vessel classification, and ROI analysis. For all tests, the results met the Pass criteria which were pre-specified based on the results of related studies found in literature. It demonstrates that MPXA-2000 performs reliably its functions for US data.

Based on the results of non-clinical verification and validation tests, it is concluded that MPXA-2000 is safe and effective in the assessment of vessel segmentation, vessel classification, and ROI analysis

9) Summary of Clinical Tests [21 CFR 807.92(b)(2)]

This premarket submission, MPXA-2000, did not require clinical studies to support substantial equivalence.

10) Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92]

There are no significant differences between MPXA-2000 and the predicate devices, QAngio XA that would adversely affect the use of the product. It is substantially equivalent to these devices in indications for use and technology characteristics.

11) Conclusions [21 CFR 807.92(b)(3)]

Based on the information submitted in this premarket notification, the intended use/indications for use, technological characteristics, and performance testing, MPXA-2000 raises no new questions of safety and effectiveness. It is substantially equivalent to the predicative devices in safety, effectiveness, and performance.

END of 510(k) Summary