October 15, 2024

Mediimg Corporation
℅ Miso Choi
Regulatory Affairs Specialist
Mediguide, Inc.
#410, Mcluster Bldg., 17, Deogan-ro 104beon-gil
Gwangmyeong-si, Gyeonggi-do 14353
Korea, South

Re: K240385
Trade/Device Name: VINT
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: September 5, 2024
Received: September 5, 2024

Dear Miso 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Daniel M. Krainak, Ph.D.
Assistant Director
Magnetic Resonance and Nuclear Medicine Team
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
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: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K240385

Device Name
VINT

Indications for Use *(Describe)*
VINT is a software that allows for the viewing, post-processing, and quantitative evaluation of cerebrovascular MRI data (in DICOM-compliant format).

It enables:
- Importing DICOM-compliant MR Images.
- Quantitative analysis of imported images.
- Visualization and analysis of blood flow characteristics of cerebral arteries in MR images.
- Advanced correction options such as offset correction, background phase correction, and anti-aliasing.
- Data visualization as a graph or output as an image or numerical data.
- Providing the right and left carotid and vertebral arteries wall signal intensity gradient (SIG), an image-based indirect marker for velocity gradient from TOF-MRA.

VINT is intended for use with adult (22 years or more) populations who can undergo MRA.

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

K240385

September 5, 2024

## 1. Submitter Information & Contact Person


| | |
|---|---|
| Name of Manufacturer | Mediimg Corp. |
| Address | Rm 6, Startup-Center, 2F, 172, Dolma-ro, Bundang-gu, Seongnam-si, Gyeonggi-do, Republic of Korea (Zip : 13605) |
| Contact Name | Byeong-Uk Jeon / R&D manager |
| Telephone No. | +82-10-9011-9694 |
| Email Address | RND_jeon@mediimg.com |


## 2. Trade Name, Common Name, Classification

Common name: Cerebrovascular imaging software
Trade name: VINT

| Regulation Description | 21 CFR Section | Product Code |
|---|---|---|
| Medical image management and processing system | 892.2050 | LLZ |

As stated in 21 CFR parts 892.2050, devices of this type have been classified as Class II.

## 3. Identification of Predicate Device

The identified predicate devices and reference device within this submission are shown as follow:

Predicate device A

| | |
|---|---|
| 510(k) Number | K172803 |
| Applicant | Infinitt Healthcare Co.,Ltd. |
| Regulation Name | Medical image management and processing system |
| Product code | LLZ |
| Device Name | Infinitt PACS 7.0 |

Predicate device B

| | |
|---|---|
| 510(k) Number | K222854 |
| Applicant | Cardio Flow Design Inc. |
| Regulation Name | Medical image management and processing system |
| Product code | LLZ |
| Device Name | iTFlow |

Reference device

| | |
|---|---|
| 510(k) Number | K213583 |
| Applicant | Philips Medical Systems Nederland B.V. |
| Regulation Name | Magnetic resonance diagnostic |
| Product code | LNH |
| Device Name | Achieva, Ingenia, Ingenia CX, Ingenia Elition and Ingenia Ambition MR Systems |

## 4. Description of the Device

### 4.1. General description

VINT is a standalone medical software device designed for processing, analyzing, viewing, and quantifying cerebral artery MR images. The software is intended to visualize and quantify MRI data imported in DICOM format. The key functions of the VINT software are 2D and 3D viewing, multi-phase series support, zoom, pan, window level, rotate, ROI Markers: Ability to create preset shapes or freehand ROI for measurements or segmentations, provide heatmaps to help users understand the distribution of arterial signal intensity gradient at a glance, and show measured numbers in a table.

VINT is intended for use with adult (22 years or more) populations who can undergo MRA.

It can also be used to analyze multi-slice signal intensity gradient of a TOF-MRA to visualize and analyze the blood flow characteristics of cerebral arteries, without any-contrast medium for MR angiography.

Medical data (patient information, etc.) is not sent over communication channels and is used only locally.
Nevertheless, use network firewall and antivirus software to prevent patient information leakage.

### 4.2. Key Performance Specifications

The key functions of the VINT software are 2D and 3D viewing, multi-phase series support, zoom, pan, window level, rotate, ROI Markers: Ability to create preset shapes or freehand ROI for measurements or segmentations, provide heatmaps to help users understand the distribution of arterial signal intensity gradient at a glance, and show measured numbers in a table.

### 4.3. Quantitative imaging function

1) Information on signal intensity gradient (SIG)

| Contents | Operational Environment |
|---|---|
| · Equation | · SIG = (Φb − Φa)/\|Xb − Xa\|<br>· Φa, signal intensity at wall point A [Xa], Φb, signal intensity at inner-wall point B [Xb] |
| · Output | · Set of real values<br>· Unit: Signal intensity(SI)/mm |
| · SIG value (Output) display | · Provided at wall point A [Xa] |
| · Resolution | · Same as TOF-MRA (the number of pixels within a specified Field of View (FOV) |
| · validation | · 2D PC-MR velocity gradient |
| · Level of automatism | · Semi-automatic |
| · Iso-value setting for segmentation | · Semi-automatic segmentation: the threshold segmentation method by binary algorithm (default)<br>· Manual setting |

2) Information on artery degree of angle

| Contents | Operational Environment |
|---|---|
| · Equation | · The coordinates at the ends of the region of interest are denoted as $\boldsymbol{C_1} = (\boldsymbol{x_1}, \boldsymbol{y_1}, \boldsymbol{z_1}), \boldsymbol{C_2} = (\boldsymbol{x_2}, \boldsymbol{y_2}, \boldsymbol{z_2})$, The differences between these coordinates are calculated as $\boldsymbol{X} = \boldsymbol{x_2} - \boldsymbol{x_1}, \boldsymbol{Y} = \boldsymbol{y_2} - \boldsymbol{y_1}, \boldsymbol{Z} = \boldsymbol{z_2} - \boldsymbol{z_1}$.<br>A total of 6 pairs of coordinates, spaced 60 degrees apart, are used.<br>$Angle = \frac{\arccos\left(\frac{Z}{\sqrt{X^2 + Y^2 + Z^2}}\right) * 180}{\pi}$<br>· This process is repeated for each frame in the region of interest. |
| · Output | · A real value<br>· Unit: degree |
| · Angle (Output) display | · Angle of the region of interest |
| · validation | · Comparison with Predicate device Infinitt PACS |
| · Level of automation | · Semi-automatic |
| · Thresholding methods | · Vessel segmentation: Thresholding based on binarization algorithms<br>· The threshold is automatically determined through image analysis. (default)<br>· Manual threshold setting is also possible. |
| · Iso-value setting for segmentation | · Semi-automatic segmentation: Separate the background area and vessels using a binarization algorithm based on image pixel value distribution. The threshold is automatically determined through image analysis. (default)<br>· Manual threshold setting is also possible. |

3) Information on coordinate system

| Contents | Operational Environment |
|---|---|
| · Equation | · World Position =<br>· $X = Xx * i + Yx * j + Sx$<br>· $Y = Xy * i + Yy * j + Sy$<br>· $Z = Xz * i + Yz * j + Sz$<br>· (X, Y, Z)： World coordinate system<br>· (i, j)： Pixel coordinates within the image<br>· (Xx, Xy, Xz)： X-direction vector<br>· (Yx, Yy, Yz)： Y-direction vector<br>· (Sx, Sy, Sz): image position (patient)<br><br>This transformation utilizes DICOM tag information:<br>Image Position (Patient) (0020,0032): (Sx, Sy, Sz)<br>Image Orientation (Patient) (0020,0037): (Xx, Xy, Xz, Yx, Yy, Yz)<br>Pixel Spacing (0028,0030): Pixel size<br>· Length = $\sqrt{(X2 - X1)^2 + (Y2 - Y1)^2 + (Z2 - Z1)^2}$ |
| · Output | · World Position: Real-world coordinates<br>· Length: A real value, Unit: mm |
| · Output display | · Output information for each point |
| · Validation | · Comparison with Predicate device Infinitt PACS |

| Contents | Operational Environment |
|---|---|
| · Level of automation | · Semi-automatic |
| · Thresholding methods | · Vessel segmentation: Thresholding based on binaryzation algorithms |

## 4. Indications for Use

VINT is a software that allows for the viewing, post-processing, and quantitative evaluation of cerebrovascular MRI data (in DICOM-compliant format).

It enables:

- Importing DICOM-compliant MR Images.
- Quantitative analysis of imported images.
- Visualization and analysis of blood flow characteristics of cerebral arteries in MR images.
- Advanced correction options such as offset correction, background phase correction, and anti-aliasing.
- Data visualization as a graph or output as an image or numerical data.
- Providing the right and left carotid and vertebral arteries wall signal intensity gradient (SIG), an image-based indirect marker for velocity gradient from TOF-MRA.

VINT is intended for use with adult (22 years or more) populations who can undergo MRA.

## 5. Determination of Substantial Equivalence

| Sort | Proposed Device | Predicate Device A | Predicate Device B | Reference Device | SE Decision |
|---|---|---|---|---|---|
| Device Name | VINT | Infinitt PACS 7.0 | iTFlow | Achieva, Ingenia, Ingenia CX, Ingenia Elition and Ingenia Ambition MR Systems | - |
| 510(k) Number | - | K172803 | K222854 | K213583 | - |
| Classification | Same | Class II | Class II | Class II | - |
| Regulation Number | 21 CFR 892.2050 | 21 CFR 892.2050 | 21 CFR 892.2050 | 21 CFR 892.1000 | - |
| Regulation Name | Medical image management and processing system | Medical image management and processing system | Medical image management and processing system | Magnetic resonance diagnostic | - |
| Product Code | LLZ | LLZ | LLZ | LNH | - |
| Intended Use | VINT is a software that allows for the viewing, post-processing, and quantitative evaluation of cerebrovascular MRI data (in DICOM-compliant format).<br>It enables:<br>- Importing DICOM-compliant MR Images.<br>- Quantitative analysis of imported images.<br>- Visualization and analysis of blood flow characteristics of cerebral arteries in MR images.<br>- Advanced correction options such as offset correction, background phase correction, and anti-aliasing.<br>- Data visualization as a graph or output as an image or numerical data.<br>- Providing the right and left carotid and vertebral arteries wall signal intensity gradient (SIG), an image-based indirect marker for velocity gradient from TOF-MRA.<br><br>VINT is intended for use with adult (22 years or more) populations who can undergo MRA | Infinitt PACS 7.0, is a software device that receives medical images and data from various imaging sources. Images and data can be stored, communicated, processed, and displayed within the system or across computer networks at distributed locations.<br>Only preprocessed DICOM for presentation images can be interpreted for primary image diagnosis in mammography. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations.<br>Mammographic images may only be interpreted using a monitor that meets technical specification identified by FDA.<br>Typical users of this system are trained professionals, e.g. physicians, radiologists, nurses, and medical technicians. | The iTFlow software will be utilized in situations where visualization of blood flow in a heart and its major vessels are required for a cardiac diagnosis. iTFlow allows for the viewing, post-processing, and the quantitative evaluation of cardiovascular MRI data (in DIRECTOR-compliant format)<br>It enables:<br>- The import of DICOM-compliant MR Images.<br>- The support of a clinical diagnosis by the quantitative analysis of the imported images.<br>- Quantitative measurement of the size, area, blood flow, volume and mass of the heart and adjacent vessels.<br>-Advanced correction options such as offset correction, background phase correction, and anti-aliasing.<br>-Data visualization as a graph or output as an image or numerical data.<br>iTFlow software will assist clinicians with proper training in cardiac treatment decision making and in providing a conclusive diagnosis for patients. It is intended to analyze cardiovascular MRI image data, that are acquired via electrocardiogram gated | Philips Magnetic Resonance (MR) systems are Medical Electrical Systems indicated for use as a diagnostic device. This MR system enables trained physicians to obtain cross-sectional images, spectroscopic images and/or spectra of the internal structure of the head, body or extremities, in any orientation, representing the spatial distribution of protons or other nuclei with spin.<br>Image appearance is determined by many different physical properties of the tissue and the anatomy, the MR scan technique applied, and presence of contrast agents. The use of contrast agents for diagnostic imaging applications should be performed consistent with the approved labeling for the contrast agent.<br>The trained clinical user can adjust the MR scan parameters to customize image appearance, accelerate image acquisition and synchronize with the patient's breathing or cardiac cycle.<br>The systems can use combinations of images to produce physical parameters, and related derived images. Images, | Similar |

| | | | | | |
|---|---|---|---|---|---|
| | | | acquisition, gradient echo cine sequence, and phase contrast time-resolved multi-slice sequence, without any-contrast medium for MR angiography. Patient populations are not restricted. | spectra, and measurements of physical parameters, when interpreted by a trained physician, provide information that may assist diagnosis and therapy planning. The accuracy determined physical parameters depends on system and scan parameters, and must be controlled and validated the clinical user. In addition the Philips MR systems provide imaging capabilities, such as MR fluoroscopy. to guide and evaluate interventional and minimally invasive procedures in the head, body and extremities. MR Interventional procedures, performed inside or adjacent to the Philips MR system, must be performed with MR Conditional or MR Safe instrumentation as selected and evaluated by the clinical user for use with the specific MR system configuration in the hospital. The appropriateness and use of information from a Philips MR system for a specific interventional procedure and specific MR system configuration must be validated by the clinical user. | |
| Areas of Use | Radiology | Radiology | Radiology | Radiology | Same |
| Data Source | TOF-MRA | TOF-MRA, PC-MR, MRI | TOF-MRA, PC-MR (4D Flow) | TOF-MRA, PC-MR, MRI | Same |
| Target Organ/ System | Cerebrovascular | Brain, body, extremities | Cardiovascular | Brain, body, extremities | Different |
| DICOM formats | DICOM 3.x | DICOM 3.x | DICOM 3.x | DICOM 3.x | Same |
| Key Functionality / Features | • 2D and 3D viewing, multi-phase series support, zoom, pan, window level, rotate<br>• ROI Markers: Ability to create preset shapes or freehand ROI for measurements or segmentations<br>• Provide heatmaps to help | • 2D and 3D viewing, multi-phase series support, zoom, pan, window level, rotate<br>• ROI Markers: Ability to create preset shapes or freehand ROI for measurements or segmentations | • 2D, 3D and 4D viewing, multi-phase series support, zoom, pan, window level, rotate<br>• ROI Markers: Ability to create preset shapes or freehand ROI for measurements or segmentations<br>• Provide heatmaps to help | • For MR Workspace:<br>• 2D and 3D viewing, multi-phase series support, zoom, pan, window level, rotate<br>• ROI Markers: Ability to create preset shapes or freehand ROI for measurements or | Same |

| | | | | | |
|---|---|---|---|---|---|
| | users understand distribution of blood flow and signal intensity gradient at-a-glance<br>• Data visualization as an image or numerical data | • Data visualization as an image or numerical data | users understand distribution of blood flow at-a-glance<br>• Data visualization as an image or numerical data | segmentations<br>• Data visualization as an image or numerical data | |
| Segmentation of region of interest | Yes | Yes | Yes | Yes | Same |
| Nature of arterial image | Blood flow | Blood flow | Blood flow | Blood flow | Same |
| Image resolution | Same as MR image | Same as MR image | Same as MR image | Same as MR image | Same |
| Quantitative Analysis, arterial radius | Yes | Yes | Yes | Yes | Same |
| Quantitative Analysis, Velocity gradient | • Yes<br>• Signal intensity gradient (difference of signal intensity/radius) to substantiate velocity gradient | N/A | • Yes<br>• Velocity gradient as a function of velocity/radius | • Yes<br>• Velocity gradient can be calculated as it outputs velocity and radius information | Same with predicate device B and Reference Device |
| Interpolation | • Trilinear interpolation | N/A | • Interpolation methods including trilinear or Lagrangian, used variously | N/A | Same with predicate device B |
| Calculated inner distance from vessel surface | • 0.03mm (default) | N/A | • Usually not-reported (hidden) | N/A | Different |
| Quantitative analysis, angle | Yes | Yes | Yes | Yes | Same |
| Quantitative analysis, length | Yes | Yes | Yes | Yes | Same |
| Quantitative analysis, volume | Yes | Yes | Yes | Yes | Same |

## 6.1. Comparison between Subject and Predicate Devices

**SIMILARITIES TO PREDICATE DEVICES**

Subject device provides identical qualitative (2D/3D viewing) and quantitative analysis data for arterial length, angle, radius, and volume compared to the predicate device A. Additionally, subject device shares the same intended use with the three predicate devices: visualizing vascular Magnetic Resonance (MR) images in the field of radiology as a graph or outputting them as an image or numerical data. A rigorous comparison of key parameters, including data source, DICOM format, core functionalities, segmentation capabilities, image characteristics, resolution, and quantitative analysis metrics such as arterial radius, length, angle, and volume, has demonstrated that Subject device is substantially equivalent to the predicate devices.

In terms of velocity gradient and interpolation, subject device exhibits performance similar to predicate device B.

Subject device provides the same quantitative analysis data for arterial length, angle, radius, and volume as predicate device A.

**DIFFERENCES TO PREDICATE DEVICES**

Correlation between TOF-MRA and PC-MR

The SIG obtained from TOF-MRA showed a highly significant correlation with the velocity gradient calculated from PC-MR. This indicates that TOF-MRA provides information similar to that of PC-MR.

Difference from Predicate B (K222854)

The difference between subject device and the approved device B: K222854 is that the SIG from VINT is based solely on TOF-MRA, whereas the velocity gradient from the approved device B: K222854 is based on both TOF-MRA and PC-MR.

Validation of TOF-MRA SIG for velocity gradient from PC-MR

Bench tests were performed using the subject device and the reference device (K213583) to validate TOF-MRA SIG as a reliable measure of shear rate obtained from PC-MR data. The SIG from TOF-MRA showed highly significant correlations with velocity gradient calculated from the PC-MR, both in tubal experiments and human studies. TOF-MRA is an examination for blood flow and the signal intensities can be used to derive arterial SIG, an image-based indirect marker for velocity gradient.

## 7. Performance verification

**Non-Clinical Test Summary**

Bench testing was conducted with Predicate Device A to evaluate general performance metrics, including arterial length, angle, radius, and volume. To assess the correlation between the velocity gradient from PC MR data and the signal intensity (SIG) from TOF-MRA, a comparative validation was performed between the subject device and the reference device.

Additionally, the software validation activities and cybersecurity assessment and testing were performed in accordance with IEC 62304:2006 Ed. 1.1 Medical device software – Software life cycle processes, FDA Guidance documents, "Content of Premarket Submissions for Device Software Functions", "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" and AAMI TIR57:2016 - Principles For Medical Device Security – Risk Management.

**Clinical Test Summary**

No clinical studies are considered necessary and performed.

**Conclusion**

The differences observed have been validated through comparative verification and do not raise any new potential safety risks. Therefore, there is no impact on the safety or efficacy of the subject device when compared to the predicate devices. Consequently, the subject device is substantially equivalent to the predicate devices.