November 8, 2021

Hura Imaging, Inc.
% Andrew Wu
Branch Manager and Software Consultant
Rook Quality Systems, Inc.
1155 Mount Vernon Highway, Suite 800
DUNWOODY GA 30338

Re: K212550
Trade/Device Name: Hura CTP v1.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: July 30, 2021
Received: August 13, 2021

Dear Andrew Wu:

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,

, for

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212550

Device Name
Hura CTP™ v1.0

Indications for Use *(Describe)*
Hura CTP™ v1.0 is intended as an image processing software to reduce noise of head CT Perfusion (CTP) DICOM images through multiple algorithm steps.

The software reduces image noise and enhances image contrast (e.g. contrast-to-noise ratio (CNR) and signal-to-noise ratio (SNR)) of the CTP DICOM images. Hura CTP™ v1.0 is non-iterative; hence the low computational overhead enables fast processing and allows no interruption to clinical workflow.

Hura CTP™ v1.0 outputs head CTP DICOM images with enhanced image quality to a designated directory defined by the user. The processed DICOM images can be imported to a third-party post-processing software for quantification of hemodynamic parameters.

The use of this algorithm may enhance the image contrast of head CTP DICOM images depending on the clinical task, patient size, and clinical practice. A consultation with a radiologist and a physicist should be made to determine the appropriate imaging protocol to obtain diagnostic image quality for the clinical task.

Hura CTP™ v1.0 is intended for use only by trained and qualified clinical personnel (e.g. radiologists). Hura CTP™ v1.0 is also intended to be used by trained and qualified personnel for installation and maintenance of the software.

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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V. 510(k) Summary K212550

Date Prepared

July 30th, 2021

Manufacturer and 510(k) Owner

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Device Information

Trade/Proprietary Name	Hura CTP™ v1.0
Common Device Name	Image Processing System
Classification Name	Medical Image Management and Processing System
Regulation Number	21 CFR 892.2050
Product Code(s)	LLZ
Classification	Class II
Review Panel	Radiology
Use	Prescription

Indications for Use

Hura CTP™ v1.0 is intended as an image processing software to reduce noise of head CT Perfusion (CTP) DICOM images through multiple algorithm steps.

The software reduces image noise and enhances image contrast (e.g. contrast-to-noise ratio (CNR) and signal-to-noise ratio (SNR)) of the CTP DICOM images. Hura CTP™ v1.0 is non-iterative; hence the low computational overhead enables fast processing and allows no interruption to clinical workflow.

Hura CTP™ v1.0 outputs head CTP DICOM images with enhanced image quality to a designated directory defined by the user. The processed DICOM images can be imported to third-party post-processing software for quantification of hemodynamic parameters.

The use of this algorithm may enhance the image contrast of head CTP DICOM images depending on the clinical task, patient size, and clinical practice. A consultation with a radiologist and a physicist should be made to determine the appropriate imaging protocol to obtain diagnostic image quality for the clinical task.

Hura CTP™ v1.0 is intended for use only by trained and qualified clinical personnel (e.g. radiologists). Hura CTP™ v1.0 is also intended to be used by trained and qualified personnel for installation and maintenance of the software.

Device Description

Hura CTP™ v1.0 is an image processing software which reduces noise of CTP DICOM images and enhances image contrast and signal-to-noise ratio. Hura CTP™ v1.0 is based on a new algorithm termed k-space weighted image average (KWIA) that was adapted from accelerated 4D dynamic MRI with projection view-sharing. There are two major advantages of KWIA compared to existing denoising method for CTP:

1) KWIA is computationally simple and fast (non-iterative); hence the low computation overhead enables fast processing and allows no interruption to clinical workflow.
2) KWIA does not make assumptions of noise characteristics and preserves the texture and resolution of CT images.

The software consists of three modules, namely the image input module, the processing module, and the output module. The image input module is responsible for interfacing with DICOM compliant CT scanners and receiving DICOM images. The image processing module is responsible for motion compensation, performing Fourier transform on DICOM images, applying KWIA, and performing inverse Fourier transform to output noise-reduced images. Both original and the noise-reduced DICOM images are then saved to the specified file directory. Hura CTP™ v1.0 is written in C/C++ language and runs as a local application on a standard PC, Mac, or UNIX workstation.

Insight Toolkit (ITK) serves as an important off-the-shelf library that KWIA algorithm leverages for a number of computational operations. The output module is responsible for transmitting noise-reduced CTP DICOM images to a designated directory defined by the user. The DICOM images can be imported to

a third-party post-processing software (e.g. iNtuition, RAPID, Vitrea, etc.) for quantification of hemodynamic parameters. The software should be used only by trained professionals including, but not limited to, physicians, medical physicists, and technicians.

Technological Characteristics

The Hura CTP™ v1.0 is a software only device that runs on standard workstations running Windows, Mac OS X, and Unix.

The Hura CTP™ v1.0 receives head CT Perfusion (CTP) DICOM images from local workstation then applies the KWIA algorithm to reduce noise and enhance contrast of the input images. Processed image files are stored on the local workstation along with a file containing motion metrics, if requested.

The device does not contact the patient, nor does it control any life-sustaining devices. Information provided by the Hura CTP™ v1.0 is not intended in any way to eliminate, replace, or substitute for, in whole or in part, the healthcare provider's judgment and analysis of the patient's condition.

Equivalence to Predicate Device

Hura Imaging submits the following information to demonstrate that the Hura CTP™ v1.0 is substantially equivalent to the following legally marketed predicate device:

510(k) Number	K063391
Predicate Device Name / Manufacturer	Sapheneia Clarity™ / Sapheneia Commercial Products AB
Regulation Number	CFR 892.2050
Regulation Name	Picture Archiving and Communications System
Regulatory Class	Class II
Primary Product Code	LLZ

The subject device has the same intended use and similar technological characteristics in comparison with the primary predicate device (K063391). Sapheneia Clarity™ (K063391) is an image processing software which reduces noise and enhances contrast of relative structures. Thus, the intended use is the same.

Hura Imaging believes the following technological similarities are shared by the subject and predicate device:

- Both the subject and predicate device are post-processing software devices which run on off-the-shelf operating system and intend to employ noise reduction techniques to achieve contrast enhancement on DICOM images.
- Both the subject and predicate device are intended for use only by trained and qualified clinical personnel (e.g. radiologists).
- Both the subject and predicate device are adapted to existing radiology departmental workflow.
- Both the subject and predicate device process DICOM-compliant image data.

Hura Imaging believes the following technological differences between the subject and the predicate device do not raise further questions or concerns on the safety and effectiveness of the subject device.

- Location of image processing enhancement engine: Subject device is installed as local application on the desktop computer onsite (e.g. hospital facility) whereas the predicate device is installed at the server onsite (e.g. hospital facility). This technological difference does not raise new issues of safety and effectiveness as compared to the predicate device.

- Modalities: Subject device receives head CT Perfusion images from commercial CT scanners which meet the criteria for scanner characteristics defined in the instructions for use (e.g. gantry aperture >= 70cm, No. of rows >= 16, power output >= 40kW, tube voltage >= 80kVp, tube current >= 30mA, reconstruction matrices >= 512x512, scan FOV >= 18cm), whereas the predicate system receives images from a variety of diagnostic systems. In addition, the compatible CT scanners shall acquire images which meet the criteria for image characteristics defined in the instructions for use (e.g. file format, pixel size, number of slice, number of time frames, and presence of artifact). Verification tests were carried out to demonstrate that the subject device demonstrate compatibility to scanners and the software can achieve its intended use. Hence, this technological difference does not raise new issues of safety and effectiveness as compared to the predicate device.

- User Interface: Subject device does not have graphic user interface and the processed images are reviewed on existing PACS workstation whereas the predicate device likely has user interface to allow viewing of multi-modality images. Both the subject device and predicate device are intended to be used by trained/qualified personnel for installation and maintenance of the software. Subject device runs as a local application that receives a copy of DICOM digital medical image data from the modality or another DICOM source, processes the data and then outputs the noise-reduced image as a local file. The original images are not replaced or removed. The noise-reduced, output image will be labeled distinctively to avoid confusion to the user. This technological difference does not raise new issues of safety and effectiveness as compared to the predicate device.

- Operating System: Subject device can be operated on Windows, Mac OS X, and Unix whereas the predicate device can be operated on Windows. Verification tests were carried out to demonstrate that the subject device achieves its intended use on all the operation systems. Hence, this technological difference does not raise new issues of safety and effectiveness as compared to the predicate device.

- CT Acquisition Protocol: Subject device is a post-processing software to reduce noise and enhance contrast of relevant structures of images acquired via standard CTP acquisition protocol whereas the predicate device is a post-processing software to reduce noise and enhance contrast of relevant structures of images acquired via predefined or specific acquisition protocol. This technological difference does not raise new issues of safety and effectiveness as compared to the predicate device.

- Image Enhancement Algorithm: Subject device employs analysis of spatial frequencies of CTP images and enhances the CTP signal through spatial and temporal filtering in the frequency domain that preserves the fidelity of dynamic perfusion signal while simultaneously reducing the noise. Predicate device employs analysis of the image structure in the neighborhood of each pixel. The dominant structure can be distinguished by estimate methods from embedding noise, and further strengthened to improve SNR. This technological difference does not raise new issues of safety and effectiveness as compared to the predicate device.

Hura Imaging plans to include the following reference device to support the substantially equivalent decision:

510(k) Number	K131447
Reference Device Name / Manufacturer	iNtuition/ TeraRecon, Inc.
Regulation Number	CFR 892.2050
Regulation Name	Picture Archiving and Communications System
Regulatory Class	Class II
Primary Product Code	LLZ

The reference device serves as a tool to generate multi-parametric perfusion maps for performance comparison. Inclusion of the reference device in performance comparison study ensures that the diagnostic quality of the multi-parametric perfusion map is not negatively impacted by the denoising technique proposed by Hura Imaging. Hura Imaging believes that the iNuition's performance is generalizable across scanners and protocols for which the subject device is claimed compatible with. Hura Imaging chose iNtuition for our performance validation studies because it can be applied for the analysis of both CTP phantom and clinical CTP data acquired from 9 CT scanners by 4 main manufacturers (GE, Philips, Siemens, Toshiba) to generate multi-parametric perfusion maps.

Hura Imaging believes that the Hura CTP™ v1.0 described in this notification and for use under the conditions of the proposed labeling is substantially equivalent to the legally marketed predicate device (K063391) based on the information summarized in the following Table 1 – Substantial Equivalence Summary.

Table 1 – Substantial Equivalence Summary

Topic	**Predicate Device (Sapheneia Clarity™, K063391)**	**Subject Device (Hura CTP™ v1.0, K212550)**
Physical Characteristics	Software package that operates on off-the-shelf hardware	Same
Computer	PC Compatible	Same
Image Processing Enhancement Location	Onsite on the desktop computer server	Onsite on the desktop computer as local application
DICOM Standard Compliance	The software processes DICOM compliant image data	Same
Operating System	Windows	Windows, Mac OS X, and Unix

Modalities	Multi-modality	Head CT Perfusion images
User Interface	The software is designed for use on a radiology workstation. It is unknown whether there is a user interface.	None – enhanced images are viewed on existing PACS workstations
Protocols	Predefined or specific acquisition protocol settings	Standard clinical CTP protocols
Image Enhancement Algorithm Description	Sapheneia Clarity™ employs a sophisticated statistical analysis of the image structure in the neighborhood of each pixel. Using robust estimation methods, the dominant structures are separated from the embedding noise. Once the structure has been determined, it is possible to strengthen the interesting parts while simultaneously reducing the noise.	Hura CTP™ v1.0 employs analysis of spatial frequencies of CT perfusion (CTP) images and enhances the CTP signal through spatial and temporal filtering in the frequency domain that preserves the fidelity of dynamic perfusion signal while simultaneously reducing the noise.
Image Acquisition	The acquisition remains the same, i.e. the image processing can be generated from multiple modalities and with predefined or specific acquisition protocol settings.	Same

Performance Data

The subject device is designed in conformance with:

- NEMA PS 3.1 - 3.20 (2016) Digital Imaging and Communications in Medicine (DICOM) Set
- ISO 14971:2019 – Medical Devices – Application of Risk Management to Medical Devices
- IEC 62304:2006/AMD 1:2015 – Medical Device Software – Software Life-Cycle Processes
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- Guidance for General Principle of Software Validation; Final Guidance for Industry and FDA Staff
- Guidance for Off-the-Shelf Software Use in Medical Devices
- Guidance for the Content of Premarket Submission for Management of Cybersecurity in Medical Devices
- Guidance for Software as Medical Device (SAMD): Clinical Evaluation

All specifications of the Hura CTP™ v1.0 are verified by a number of tests before release. Bench testing including verification tests on:

- DICOM image import and export
- Command line functions
- Image denoising and contrast enhancement
- Motion correction and export metrics

A phantom validation study and a validation study with simulated small feature inserted were conducted for validating Hura CTP™ v1.0.

For CTP phantom DICOM images acquired on both Philips Brilliance and Toshiba Aquilion scanners, noise standard deviation (SD) values were significantly reduced using Hura CTP™ v1.0 compared to those by the vendor. The average SNR increased from 4.89±2.13 to 7.91±3.38 (62% increase, P<0.01) for Philips and from 6.88±2.88 to 9.83±3.76 (43% increase, P<0.01) for Toshiba, and the average CNR increased from 1.13±0.62 to 1.81±0.95 (60% increase, P<0.01) for Philips and from 1.76±0.94 to 2.51±1.25 (43% increase, P<0.01) for Toshiba using Hura CTP™ v1.0 compared to the vendor. The normalized root mean square error (NRMSE) of time density curves (TDCs) of two tissue regions as well as the artery and vein were all within 5% for 30 CTP phantom scans acquired on both Philips Brilliance and Toshiba Aquilion scanners at 5 perfusion rates and 6 radiation dose (RD) levels. For parametric perfusion maps of CTP phantom DICOM images acquired on the Philips Brilliance and Toshiba Aquilion scanners, the mean tissue SNR values of CBV, Tmax and TTP maps all significantly increased from 5% to 16% (P<0.01) using Hura CTP™ v1.0 compared to vendor generated DICOM images. Furthermore, all intra-class correlation coefficient (ICC) values including 95% CI were excellent (all estimated ICC values ≥ 0.86 with lower bounds of 95% CI ≥ 0.78) for perfusion parameters generated using Hura CTP™ v1.0 processed and vendor DICOM images.

For the 40 CTP datasets of two clinical cases with inserted simulated small objects acquired on Siemens Sensation and Toshiba Aquilion scanners, the average SNR of the inserted small object increased from 12.31±6.76 to 13.35±7.32 (8.4% increase, P<0.01) using DICOM imaging processed with Hura CTP™ v1.0 compared to those without Hura CTP™ v1.0 processing. The NRMSE of TDCs of the small object were all within 5% for the 40 CTP datasets of the two clinical cases. For parametric perfusion maps of the 40 CTP datasets, all ICC values including 95% CI were excellent (all estimated ICC values ≥ 0.94 with lower bounds of 95% CI ≥ 0.89) for perfusion parameters generated using DICOM images with and without post-processing using Hura CTP™ v1.0.

Clinical Data

A retrospective clinical study was conducted for validating HuraCTP™ V1.0.

For the 40 datasets of clinical DICOM images acquired at the 4 sites on CT scanners manufactured by the 4 OEMs, the SD values of both grey and white matter were significantly reduced using Hura CTP™ v1.0 compared to those by the vendor. The average SNR increased from 4.8±1.16 to 7.12±1.73 (48% increase, P<0.01) for grey matter and from 3.43±0.71 to 5.57±1.25 (62% increase, P<0.01) for white matter, and the average CNR between grey and white matter increased from 1.03±0.51 to 1.55±0.72 (50% increase, P<0.01) using Hura CTP™ v1.0 compared to the vendor. The NRMSE of TDCs of grey and white matter as well as the artery and vein were all within 5% for the 40 CTP scans acquired at the 4 sites. For quantitative parametric perfusion maps of DICOM images acquired at the 4 sites, the mean SNR values of both grey and white matter CBF, white matter CBV, and grey and white matter TTP all significantly increased from 1.4% to 5% (P<0.01) using Hura CTP™ v1.0 compared to vendor generated DICOM images. For parametric perfusion maps of DICOM images acquired at the 4 sites, all ICC values including

95% CI were excellent (all estimated ICC values ≥ 0.88 with lower bounds of 95% CI ≥ 0.8) for perfusion parameters generated using Hura CTP™ v1.0 processed and vendor DICOM images.

Hura Imaging believes that the aforementioned non-clinical testing and clinical validation demonstrate that the subject device is designed in such a way that, when used under the conditions and for the purposes intended, the safety and effectiveness, as well as the performance characteristic of the subject device is substantially equivalent to the predicate device.

Substantial Equivalence Conclusion

Hura Imaging has the same intended use and performance characteristics as the predicate device. Based on the software verification performed, it can be concluded that the differences in technological characteristics between the Hura CTP™ v1.0 and the predicate device do not raise different questions of safety and effectiveness under specified use conditions. The indications for use, technological characteristics, and performance characteristics for the Hura CTP™ v1.0 are assessed to be substantially equivalent to the predicate device. There is no identified hazard that requires additional benefit versus risk analysis in support of substantial equivalence.