Shanghai United Imaging Healthcare Co., Ltd.
% Xin GAO
Regulatory Affairs Manager
No. 2258 Chengbei Road
Shanghai, Shanghai 201807
CHINA

April 30, 2021

Re: K210001
Trade/Device Name: HYPER AiR
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: Class II
Product Code: KPS
Dated: March 27, 2021
Received: March 30, 2021

Dear Xin GAO:

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)*
K210001

Device Name
HYPER AiR

Indications for Use *(Describe)*
HYPER AiR is an image processing function intended to be used by radiologists and nuclear medicine physicians to reduce noise and improve contrast of fluorodeoxyglucose (FDG) PET images.

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. Date of Preparation

March 26, 2021

2. Sponsor Identification

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3. Identification of Proposed Device

Trade Name: HYPER AiR
Common Name: Emission Computed Tomography System
Model(s): HYPER AiR

Regulatory Information
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission Computed Tomography System
Regulatory Class: II
Product Code: KPS
Review Panel: Radiology

4. Identification of Predicate Device(s)

Predicate Device
510(k) Number: K193241
Device Name: Emission Computed Tomography System
Model(s): uMI 550

Regulatory Information
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission Computed Tomography System
Regulatory Class: II
Product Code: KPS, JAK
Review Panel: Radiology

5. Device Description:

HYPER AiR is a software-only device. HYPER AiR is an image reconstruction technique which incorporates pre-trained neural networks in the iteration reconstruction process to control image noise and contrast. It is intended to be

implemented on previously cleared PET/CT devices uMI 550 (K193241) and uMI 780 (K172143). HYPER AiR serves as an alternative to the existing image reconstruction algorithm that are available on the predicate devices.

6. Indications for Use

HYPER AiR is an image processing function intended to be used by radiologists and nuclear medicine physicians to reduce noise and improve contrast of fluorodeoxyglucose (FDG) PET images.

7. Comparison of Technological Characteristics with the Predicate Devices

A comparison between the technological characteristics of proposed and predicate devices is provided as below.

ITEM	Predicate Device uMI 550 (K193241)	Proposed Device HYPER AiR	Remark
Image Processing Location	Onsite on the facility PET/CT reconstruction computer.	Onsite on the facility PET/CT reconstruction computer.	Same
Operating system	Windows	Windows	Same
Workflow	Support online & offline	Support online & offline	Same
Protocols	Standard scanner protocols	Standard scanner protocols	Same
Algorithm	OSEM included in uMI 550 uses maximum-likelihood estimation techniques by maximizing the probability to the given counts represented by the image corresponding to the true activity distribution in the source, under a Poisson probability model for the positron emission. To accelerate convergence speed, it divides the projection data into a limited number of subsets and accesses them in order for iterative calculation.	HYPER AiR is a modification of conventional OSEM by incorporating the pre-trained convolutional neural networks into the iteration process.	OSEM included in uMI 550 uses maximum-likelihood estimation techniques. But HYPER AiR incorporates convolutional neural networks into OSEM to help to reconstruct PET images. Convolutional neural network is able to distinguish the noise component and the image details, and removes the noise component from the image or enhances the image details. So HYPER AiR can produce lower noise and higher contrast PET images than OSEM. Performance Evaluation Report and Clinical Image

			Evaluation show that it's safe and effective.

HYPER AiR utilizes the same hardware with the predicate devices and does not introduce any new restrictions on use. The differences do not affect the safety and the effectiveness.

8. Performance Data

Non-Clinical Testing

Non-clinical testing including image performance tests and clinical image evaluation were concluded for the HYPER AiR during the product development. UNITED IMAGING HEALTHCARE claims conformance to the following standards and guidance:

Software

- NEMA PS 3.1-3.20(2011): Digital Imaging and Communications in Medicine (DICOM)
- IEC 62304: Medical Device Software - software life cycle process
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices

Other Standards and Guidance

- ISO 14971: Medical Devices – Application of risk management to medical devices
- Code of Federal Regulations, Title 21, Part 820 - Quality System Regulation

Software Verification and Validation

Software documentation for a Moderate Level of Concern software per FDA Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" is included as a part of this submission. The risk analysis was completed and risk control was implemented to mitigate identified hazards. The testing results show that all the software specifications have met the acceptance criteria. Verification and validation testing of the proposed device was found acceptable to support the claim of substantial equivalence. UNITED IMAGING HEALTHCARE conforms to the Cybersecurity requirements by implementing a process of preventing unauthorized access, modification, misuse or denial of use, or unauthorized use of information that is stored, accessed, or transferred from a medical device to an external recipient. Cybersecurity information in accordance with guidance document "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" is included in this submission.

Performance Verification

Engineering bench testing was performed to support substantial equivalence and the product performance claims. The evaluation and analysis used the identical raw datasets obtained on UIH's uMI 780 and uMI 550, and then applies both HYPER AiR and OSEM to do image reconstruction. The resultant images were then compared for:

- Performance on noise reduction
- Performance on image contrast
- Performance on contrast to noise ratio

Performance tests have been conducted to show that HYPER AiR can improve image contrast while suppressing background noise.

Clinical Image Evaluation

The clinical image evaluation was performed by comparing HYPER AiR with OSEM. Each image was read by three board-certified nuclear medicine physicians who provided an assessment of image contrast, image noise and image quality. The results of the evaluation indicated that HYPER AiR produces images with better image contrast and lower image noise than OSEM while the image quality was sufficient for clinical diagnosis.

9. Conclusions

Based on the comparison and analysis above, the proposed device has similar performance, equivalent safety and effectiveness as the predicate devices. The differences between the proposed device and predicate devices do not affect the indications for use, safety and effectiveness. And no issues are raised regarding to safety and effectiveness. The proposed device is determined to be Substantially Equivalent (SE) to the predicate devices.