Shanghai United Imaging Healthcare Co.,Ltd.
% Xin Gao
Regulatory Affairs Manager
No. 2258 Chengbei Rd., Jiading Industrial District
Shanghai, Shanghai 201807
CHINA

April 9, 2021

Re: K210418
Trade/Device Name: HYPER Focus
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: Class II
Product Code: KPS
Dated: February 7, 2021
Received: February 11, 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)*
K210418

Device Name
HYPER Focus

Indications for Use *(Describe)*
HYPER Focus can be used to correct respiratory motion in PET images. Relative to non - corrected images, HYPER Focus can reduce respiratory motion effects and thus improve the measurement accuracy of SUV and lesion volume.

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

K210418

1. Date of Preparation

February 7, 2021

2. Sponsor Identification

Shanghai United Imaging Healthcare Co.,Ltd.
No.2258 Chengbei Rd. Jiading District, 201807, Shanghai, China

Contact Person: Xin GAO
Position: Regulatory Affairs Manager
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3. Identification of Proposed Device

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

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: K113408
Device Name: Emission Computed Tomography System
Model(s): GE Q.Freeze software

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

5. Device Description:

HYPER Focus is a software-only device. It is intended to be implemented on previously cleared PET/CT devices uMI 550 (K193241) and uMI 780 (K172143). HYPER Focus serves as an additional function for uMI 550 and uMI 780 to carry

the respiratory correction. It uses the similar respiratory motion correction technique, non-rigid image registration, as the predicate device.

6. Indications for Use

HYPER Focus can be used to correct respiratory motion in PET images. Relative to non-corrected images, HYPER Focus can reduce respiratory motion effects and thus improve the measurement accuracy of SUV and lesion volume.

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 Q.freeze Software (K113408)	Proposed Device HYPER Focus	Comment
Product Code	KPS	KPS	same
Regulation Number	21 CFR 892.1200	21 CFR 892.1200	same
Regulatory Class	II	II	same
Indications for Use	MotionVUE2 (Q.freeze) is a PET/CT, no-invasive image analysis software application designed to support the viewing and manipulation of medical images from PET and CT imaging modalities. MotionVUE2 (Q.freeze) offers processing tools to optimize workflow of respiratory gated exams for PET, CT and fused images of respiratory gated datasets for simultaneous viewing in multi-planar volumes and cine loops. MotionVUE2 (Q.freeze) allows the users to generate from their 4D-PET or 4D-PET/CT series a registered 4D-PET series used for quantification of lesions and analysis of functional activity. With MotionVUE2 (Q.freeze), users will have the possibility to compare static PET/CT, 4D-PET/CT, and registered 4DPET series including visual comparison, quantification of lesions and analysis of functional activity. MotionVUE2 (Q.freeze) provides registration performance of up to 2mm of center of mass motion when motion is no larger than the diameter of the object. MotionVUE2 (Q.freeze) provides comparable/equivalent improvement of quantification results (SUV and size) as 4D PET techniques. MotionVUE2 (Q.freeze) can be used for features with locally concentrated activity within the entire	HYPER Focus can be used to correct respiratory motion in PET images. Relative to non-corrected images, HYPER Focus can reduce respiratory motion effects and thus improve the measurement accuracy of SUV and lesion volume.	HYPER Focus is equivalent to the function of respiratory motion correction of Q.freeze. Both devices improve the SUV and lesion volume.

	Thorax area. This area includes the organs where PET/CT imaging has the most challenges due to respiratory motion: Lung, Liver, Pancreas.		
Algorithm	GE Healthcare Q.freeze software is designed to minimize the effect of respiratory motion using a non-rigid optical flow registration technique to create a single static image containing 100% of acquired counts.	HYPER Focus is a respiratory motion correction technique based on the non-rigid image registration, which is capable of correcting motion effects, eliminating the activity-attenuation mismatch artifacts, as well as improving the accuracy of SUV and lesion volume. It also utilizes 100% of the acquired data counts.	HYPER Focus has the equivalent technological characteristic to the function of respiratory motion correction of Q.freeze. Both devices are based on non-rigid image registration technique.

HYPER Focus has the equivalent technological characteristic to the function of respiratory motion correction of predicate device and does not introduce any new restrictions on use. HYPER Focus is as safe and effective as the predicate.

8. Performance Data

Non-Clinical Testing

Image performance tests were conducted for HYPER Focus 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 product performance claims. The evaluation and analysis used the identical raw datasets obtained from UIH's uMI 780 (K172143) and uMI 550 (K193241), and then respectively performed image reconstruction with/without HYPER Focus.

Bench test shows that HYPER Focus can reduce respiratory motion effects and improve the accuracy of SUV and sphere volume in comparison with no motion correction.

9. Conclusions

HYPER Focus has the equivalent technological characteristic to the function of respiratory motion correction of predicate device and does not introduce any new restrictions on use. HYPER Focus is substantially equivalent as safe as the legally marketed predicate device.

HYPER Focus is developed under UIH's quality management system. Design verification, along with bench testing demonstrates that HYPER Focus is substantially equivalent as effective as the legally marketed predicate device.

Based on the comparison and analysis above, the proposed device has similar performance, equivalent safety and effectiveness as the predicate device. 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 safety and effectiveness. The proposed device is determined to be Substantially Equivalent (SE) to the predicate devices.