



Shanghai United Imaging Healthcare Co., Ltd.  
% Shumei Wang  
QM & RA VP  
No. 2258 Chengbei Road, Jiading Industrial District  
Shanghai, Shanghai 201807  
CHINA

August 4, 2020

Re: K193210  
Trade/Device Name: HYPER DLR  
Regulation Number: 21 CFR 892.1200  
Regulation Name: Emission computed tomography system  
Regulatory Class: Class II  
Product Code: KPS  
Dated: June 24, 2020  
Received: June 29, 2020

Dear Shumei Wang:

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](mailto: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

## Indications for Use

510(k) Number (if known)  
K193210

Device Name  
HYPER DLR

Indications for Use (Describe)

HYPER DLR is an image processing function intended to be used by radiologists and nuclear medicine physicians to reduce noise of the 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**

K193210

**1. Date of Preparation**

June 24, 2020

**2. Sponsor Identification**

**Shanghai United Imaging Healthcare Co.,Ltd.**

No.2258 Chengbei Rd. Jiading District, 201807, Shanghai, China

Contact Person: Shumei Wang

Position: QM&RA VP

Tel: +86-021-67076888-6776

Fax: +86-021-67076889

Email: [shumei.wang@united-imaging.com](mailto:shumei.wang@united-imaging.com)

**3. Identification of Proposed Device**

**Trade Name:** HYPER DLR

**Common Name:** Emission Computed Tomography System

**Model(s):** HYPER DLR

**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 1:**

**510(k) Number:** K172143

**Device Name:** Emission Computed Tomography System

**Model(s):** uMI 780

**Regulatory Information**

**Regulation Number:** 21 CFR 892.1200

**Regulation Name:** Emission Computed Tomography System

**Regulatory Class:** II

**Product Code:** KPS, JAK

**Review Panel:** Radiology

**Predicate Device 2:**

**510(k) Number:** K182237

**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 DLR is a software-only device. HYPER DLR is intended to be implemented on previously cleared PET/CT devices uMI 550 (K182237) and uMI 780 (K172143). HYPER DLR serves as an alternative to the existing image smoothing options that are available on the predicate devices. HYPER DLR is an image post-processing technique which uses a pre-trained neural network to predict low noise PET image from high noise PET image. After training, the network could extract the noise component from the image, thus reducing the image noise.

**6. Indications for Use**

HYPER DLR is an image processing function intended to be used by radiologists and nuclear medicine physicians to reduce noise of the 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.

<b>ITEM</b>	<b>Predicate Device 1 uMI 780 (K172143) including a post-smoothing function for PET image reconstruction</b>	<b>Predicate Device 2 uMI 550 (K182237) including a post-smoothing function for PET image reconstruction</b>	<b>Proposed Device HYPER DLR</b>	<b>NOTE</b>
Image Processing Location	Onsite on the facility PET/CT reconstruction computer.	Onsite on the facility PET/CT reconstruction computer.	Onsite on the facility PET/CT reconstruction computer.	Same
Operating system	Windows	Windows	Windows	Same
Workflow	Support online & offline	Support online & offline	Support online & offline	Same
Protocols	Standard scanner protocols	Standard scanner protocols	Standard scanner protocols	Same
Algorithm description	The post-smoothing function uses Gaussian filtering to reduce the noise in	The post-smoothing function uses Gaussian filtering to reduce the noise in	The software employs a convolutional neural network	Gaussian filtering suppresses the high frequency

	<p>the PET images. The Gaussian filtering works by using the 3D Gaussian distribution as a point-spread function. And the filtering process is achieved by convolving the Gaussian filter with the reconstructed PET image.</p>	<p>the PET images. The Gaussian filtering works by using the 3D Gaussian distribution as a point-spread function. And the filtering process is achieved by convolving the Gaussian filter with the reconstructed PET image.</p>	<p>based method to re-generate the value for each pixel. The network extracts the noise component from the image, while retains the other useful components such as image details.</p>	<p>component of the image, which includes noise and image details. On the contrary, convolutional neural network is able to distinguish the noise component and the image details, and only removes the noise component from the image.</p>
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HYPER DLR 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 conducted for the HYPER DLR 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
- Code of Federal Regulations, Title 21, Subchapter J - Radiological Health

### 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 DLR and Gaussian filtering to do image de-noising. The resultant images were then compared for:

- Peak signal to noise ratio
- Structural similarity index
- Pearson correlation coefficient
- Signal to noise ratio (SNR)
- Contrast to noise ratio (CNR)
- Normalized root mean square error
- Bland-Altman plot of body & brain VOI SUVmean values

Bench test showed overall image quality improvement based on the commonly used quantitative metrics. HYPER DLR can significantly improve SNR and CNR while preserving image consistency.

### **Clinical Image Evaluation**

The clinical image evaluation was performed by comparing HYPER DLR with Gaussian filtering. Each image was read by board-certified nuclear medicine physicians who provided an assessment of both image noise and overall image quality. The results of the evaluation indicated that HYPER DLR performed lower image noise than Gaussian filtering while the image quality was sufficient for clinical diagnosis.

Additional clinical image evaluation were performed for typical clinical scan times of uMI 550 and uMI 780 systems. Under all the evaluated scan time, clinical evaluation shows that the HYPER DLR produces lower or equivalent image noise and better or equivalent image quality compared with Gaussian filtering. And all the HYPER DLR images are of diagnostic quality.

### **Clinical Testing**

No Clinical Study is included in this submission.

## **9. Conclusions**

The changes associated with HYPER DLR do not change the indications for use from the predicate devices, and represent equivalent technological characteristic, with no impact on control mechanism, operating principle, and energy type. HYPER DLR is substantially equivalent as safety as the legally marketed predicate devices.

HYPER DLR was developed under UIH's quality management system. Design verification, along with bench testing and the clinical image evaluation demonstrate that HYPER DLR is substantially equivalent as effective as the legally marketed predicate devices.

Based on the comparison and analysis above, the proposed device has similar performance, equivalent safety and effectiveness as the predicate devices. The differences above between the proposed device and predicate devices do not affect the intended 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.