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

July 6, 2020

Re: K193073
Trade/Device Name: Deep Recon
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: May 25, 2020
Received: May 27, 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) 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193073

Device Name
Deep Recon

Indications for Use *(Describe)*
Deep Recon is a data driven image reconstruction method based on deep learning technology. It is intended to produce cross-sectional images by computer reconstruction of X-ray transmission data taken at different angles planes, including Axial, Helical, and Cardiac acquisition.
Deep Recon is designed to generate CT images with lower image noise, and improved low contrast detectability, and it can reduce the dose required for diagnostic CT imaging.
Deep Recon can be used for head, chest, abdomen, cardiac and vascular CT applications for adults.
Deep Recon is intended to be used with uCT 760 and uCT 780 only.

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

K193073

1. Date of Preparation

May 25, 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
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Email: shumei.wang@united-imaging.com

3. Identification of Proposed Device

Trade Name: Deep Recon
Common Name: Computed Tomography X-ray System
Model(s): Deep Recon

Regulatory Information
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-ray System
Regulatory Class: II
Product Code: JAK
Review Panel: Radiology

4. Identification of Predicate Device(s)

Primary Predicate Device:

510(k) Number: K172135
Device Name: uCT Computed Tomography X-Ray System
Model(s): uCT 760, uCT 780

Regulatory Information
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-ray System
Regulatory Class: II
Product Code: JAK
Review Panel: Radiology

Secondary Predicate Device:

510(k) Number: K183202
Device Name: Deep Learning Image Reconstruction

Regulatory Information
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: II
Product Code: JAK
Review Panel: Radiology

5. Device Description:

The Deep Recon is a data driven image reconstruction method based on deep learning technology. Dedicated deep neural networks are designed and trained for different body parts. As a part of reconstruction chain, the Deep Recon generates CT images with an appearance similar to traditional FBP, but with a decreased image noise, and an improved low contrast detectability. The Deep Recon was specifically trained on uCT 760 and uCT 780 (K172135). The function is integrated on the mentioned CT systems as a part of reconstruction chain.

6. Indications for Use

Deep Recon is a data driven image reconstruction method based on deep learning technology. It is intended to produce cross-sectional images by computer reconstruction of X-ray transmission data taken at different angles planes, including Axial, Helical, and Cardiac acquisition.
Deep Recon is designed to generate CT images with lower image noise, and improved low contrast detectability, and it can reduce the dose required for diagnostic CT imaging.
Deep Recon can be used for head, chest, abdomen, cardiac and vascular CT applications for adults.
Deep Recon is intended to be used with uCT 760 and uCT 780 only.

7. Comparison of Technological Characteristics with the Predicate Devices

Specification/ Attribute	Primary Predicate Device Filtered Back Projection (FBP) on uCT 760/780 (K172135)	Secondary Predicate Device Deep Learning Image Reconstruction (K183202)	Proposed Device Deep Recon
Technology	Basic analytic reconstruction method	Utilizes a dedicated Deep Neural Network (DNN) which is trained on the CT Scanner and designed specifically to generate high quality CT images	Dedicated deep neural network (DNN) which is trained on low dose FBP images to get normal dose (high quality) FBP images
Clinical Workflow	Select recon type and convolution kernel	Select recon type and strength	Select recon type, convolution kernel and strength (noise index level)

Deep Recon utilizes the same hardware with the primary predicate device and does not introduce any new restrictions on use.

The technological characteristics of Deep Recon is substantially equivalent to the secondary predicate device Deep Learning Image Reconstruction, the differences do not affect the safety and effectiveness.

8. Performance Data

Non-Clinical Testing

Non-clinical testing including image performance tests and clinical image evaluation were conducted for the Deep Recon 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 same raw datasets obtained on UIH's uCT 760/780 and then applies both Deep Recon and Filtered Back Projection reconstruction. The resultant images were then compared for:

- Low contrast detectability (LCD) using the CCT189 MITA CT IQ low contrast phantom (The Phantom Laboratory, Salem, NY) and a model observer
- Image noise using the CCT189 MITA CT IQ low contrast phantom
- Mean CT number and uniformity using uniform water phantoms
- Spatial resolution using the Catphan 700 phantom (The Phantom Laboratory, Salem, NY) with a small diameter tungsten wire inside to generate the point spread function
- Reconstructed section thickness using the Catphan 700 phantom with a pair of tungsten ramps

Bench testing shows that the Deep Recon provides equivalent or better performance (improved LCD, decreased image noise, equivalent uniformity/spatial resolution/ reconstructed section thickness) compared to Filtered Back Projection.

Clinical Image Evaluation

The reader study used a total of 80 retrospectively collected clinical cases. The raw data from each of these cases was reconstructed with both Filtered Back Projection and Deep Recon. Each image was read by 2 board-certified radiologists who provided an assessment of both image noise and structure fidelity according to a 4-point scale (1=unacceptable for diagnostic interpretation, 2=suboptimal, acceptable for limited diagnostic information only, 3=average, acceptable for diagnostic interpretation, 4=better than usual, acceptable for diagnostic interpretation). The results of the study indicate that Deep Recon is equivalent or better than Filtered Back Projection in diagnostic quality.

An additional study used a total of 40 retrospectively collected clinical cases (20 low dose cases and 20 standard dose cases). Each of the low dose cases was reconstructed with Deep Recon and compared with standard dose case reconstructed with Filtered Back Projection. Each image was read by a board-

certified radiologist who provided an assessment of both image quality and clinical features according to a 5-point scale (1 = Unacceptable for diagnostic interpretation, 2 = Suboptimal, acceptable for limited diagnostic information only, 3 = Average, acceptable for diagnostic interpretation, 4 = Better than usual acceptable for diagnostic interpretation, 5 = Excellent for diagnostic interpretation). A comment about image quality and clinical features also left. The result of the study indicate that low dose images with Deep Recon are equivalent or better than standard dose images with Filtered Back Projection in diagnostic quality.

Clinical Testing

No Clinical Study is included in this submission.

9. Conclusions

The changes associated with Deep Recon do not change the indications for use from the primary predicate device, with no impact on control mechanism, operating principle, and energy type. Deep Recon also represents equivalent technological characteristic to the secondary predicate device.

Deep Recon was developed under UIH's quality management system. Design verification, along with bench testing and the clinical reader study demonstrate that Deep Recon is substantially equivalent and as safe and as effective as the legally marketed predicate device.

Based on the comparison and analysis above, the proposed device has similar performance, equivalent safety and effeteness as the predicate device. The differences above between the proposed device and predicate device 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 device.