



January 18, 2024

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

Re: K231762

Trade/Device Name: uEXPLORER
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission Computed Tomography System
Regulatory Class: Class II
Product Code: KPS, JAK
Dated: December 18, 2023
Received: December 18, 2023

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 (the 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 available 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 Reg

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

A handwritten signature in black ink, appearing to read 'D. Krainak', is written over a large, light blue, semi-transparent watermark of the letters 'FDA'.

Daniel M. Krainak, Ph.D.
Assistant Director
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K231762

Device Name

uEXPLORER

Indications for Use (Describe)

The uEXPLORER is a diagnostic imaging system that combines two existing imaging modalities PET and CT. The quantitative distribution information of PET radiopharmaceuticals within the patient body measured by PET can assist healthcare providers in assessing metabolic and physiological functions. CT provides diagnostic tomographic anatomical information as well as photon attenuation information for the scanned region. The accurate registration and fusion of PET and CT images provides anatomical reference for the findings in the PET images.

This system is intended to be operated by qualified healthcare professionals to assist in the detection, localization, diagnosis, staging, restaging, treatment planning and treatment response evaluation for diseases, inflammation, infection and disorders in, but not limited to oncology, cardiology and neurology. The system maintains independent functionality of the CT device, allowing for single modality CT diagnostic imaging.

This CT system can be used for low dose CT lung cancer screening for the early detection of lung nodules that may represent cancer. The screening must be performed within the established inclusion criteria of programs / protocols that have been approved and published by either a governmental body or professional medical society.*

* Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information.

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

K231762

1. Date of Preparation:

June 16, 2023

2. Sponsor Identification

Shanghai United Imaging Healthcare Co.,Ltd.

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Contact Person: Xin GAO

Position: Regulatory Affair Manager

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Email: xin.gao@united-imaging.com

3. Identification of Proposed Device

Trade Name: uEXPLORER

Common Name: Positron Emission Tomography and Computed Tomography Systems

Model(s): uEXPLORER

Regulatory Information

Regulation Number: 21 CFR 892.1200

Regulation Name: Emission Computed Tomography System

Regulatory Class: II

Product Code: KPS, JAK,

Review Panel: Radiology

4. Identification of Primary/ Reference Device(s)

Predicate Device

510(k) Number: K182938

Device Name: uEXPLORER

Regulatory Information

Regulation Number: 21 CFR 892.1200

Regulation Name: Emission Computed Tomography System

Regulatory Class: II

Product Code: KPS, JAK,

Review Panel: Radiology

Reference Device#1

510(k) Number: K193241

Device Name: uMI 550
Regulation Name: Emission Computed Tomography System
Regulatory Class: II
Product Code: KPS, JAK
Review Panel: Radiology

Reference Device#2

510(k) Number: K193210
Device Name: HYPER DLR
Regulation Name: Emission Computed Tomography System
Regulatory Class: II
Product Code: KPS
Review Panel: Radiology

Reference Device#3

510(k) Number: K230162
Device Name: uCT 780 with uWS-CT-Dual Energy Analysis
Regulation Name: Computed Tomography X-ray System
Regulatory Class: II
Product Code: JAK
Review Panel: Radiology

5. Device Description

The proposed device uEXPLORER combines a 194 cm axial field of view (AFOV) PET and multi-slice CT system to provide high quality functional and anatomical images, fast PET/CT imaging and better patient experience. The system includes PET gantry, CT gantry, patient table, power supply cabinet, console and reconstruction system, chiller, vital signal module.

The uEXPLORER has been previously cleared by FDA via K182938. The mainly modifications performed on the uEXPLORER (K182938) in this submission are due to the addition of HYPER Iterative, HYPER DLR, Digital gating, remote assistance and CT system modification.

Details about the modifications are listed as below:

- HYPER Iterative (has been cleared in K193241), uses a regularized iterative reconstruction algorithm, which allows for more iterations while keeping the image noise at an acceptable level by incorporating a noise penalty term into the objective function.
- HYPER DLR (has been cleared in K193210), uses a deep learning technique to produce better SNR (signal-to-noise-ratio).

- Digital Gating (has been cleared in K193241), uses motion correction method to provide better alternatives to reduce motion effects without sacrificing image statistics.
- Remote assistance.
- PET recon matrix: 1024×1024.
- TG-66 compliant flat tabletop.
- Update the performance according to the NEMA NU 2-2018 standard.
- Update the operation system.
- CT system modification: add Low Dose CT Lung Cancer Screening, Auto ALARA kVp, Organ-Based Auto ALARA mA, EasyRange, Injector Linkage, Shuttle Perfusion, Online MPR and Dual Energy analysis function. All functions have been cleared via K230162.

6. Indications for Use

The uEXPLORER is a diagnostic imaging system that combines two existing imaging modalities PET and CT. The quantitative distribution information of PET radiopharmaceuticals within the patient body measured by PET can assist healthcare providers in assessing the metabolic and physiological functions. CT provides diagnostic tomographic anatomical information as well as photon attenuation information for the scanned region. The accurate registration and fusion of PET and CT images provides anatomical reference for the findings in the PET images.

This system is intended to be operated by qualified healthcare professionals to assist in the detection, localization, diagnosis, staging, restaging, treatment planning and treatment response evaluation for diseases, inflammation, infection and disorders in, but not limited to oncology, cardiology and neurology. The system maintains independent functionality of the CT device, allowing for single modality CT diagnostic imaging.

This CT system can be used for low dose CT lung cancer screening for the early detection of lung nodules that may represent cancer. The screening must be performed within the established inclusion criteria of programs / protocols that have been approved and published by either a governmental body or professional medical society.*

* Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information.

7. Comparison of Technological Characteristics with the Predicate Devices

The uEXPLORER employs the same basic operating principles and fundamental technologies, and has the similar indications for use as the predicate device. A comparison between the technological characteristics of proposed and predicate devices is provided as below.

ITEM	Proposed Device	Predicate Device (K182938)
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Gantry	760 mm bore	760 mm bore
PET system	Scintillator material: LYSO Number of detector rings: 672 Axial FOV: 194 cm Gantry bore: 76 cm	Scintillator material: LYSO Number of detector rings: 672 Axial FOV: 194 cm Gantry bore: 76 cm
CT System	Cleared via K230162	Cleared via K172135
Maximum table load	250 kg	250 kg
Post-processing software		
HYPER Iterative	Yes	No
HYPER DLR	Yes	No
Digital gating	Yes	No

uEXPLORER's technological characteristics do not raise new safety and effectiveness concerns.

8. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Non-Clinical Testing

Non-clinical testing including Algorithm and Image performance tests were conducted for the uEXPLORER during the product development.

UNITED IMAGING HEALTHCARE claims conformance to the following standards and guidance:

Electrical Safety and Electromagnetic Compatibility (EMC)

- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-2-44 Edition 3.2: 2016 Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of x-ray equipment for computed tomography
- IEC 60601-1-3 Edition 2.1 2013-04 Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
- IEC 60825-1 Edition 3.0 2014 Safety of laser products - Part 1: Equipment classification, and requirements [Including: Technical Corrigendum 1 (2008), Interpretation Sheet 1 (2007), Interpretation Sheet 2 (2007)]

- IEC 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.
- IEC 62304 Edition 1.1 2015-06 Consolidated version, Medical device software - Software life cycle processes
- NEMA NU 2-2018, Performance Measurements of Positron Emission Tomographs

Software

- NEMA PS 3.1-3.20(2022d): Digital Imaging and Communications in Medicine (ICOM)
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices

Biocompatibility

- ISO 10993-1: 2018, Edition 5.0, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
- ISO 10993-5: 2009, Edition 3.0, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-10: 2010, Edition 3.0, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

Other Standards and Guidance

- ISO 14971: 2019, Edition 3.0, 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

Clinical Testing

No Clinical Study is included in this submission.

Summary

The features described in this premarket submission are supported with the results of the testing mentioned above, the uEXPLORER was found to have a safety and effectiveness profile that is similar to the predicate device.

9. Conclusions

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