FMI Medical Systems Inc.
% Paul McFeely
Quality Assurance Engineer
FMI Medical Systems, Inc.
29001 Solon Rd, Unit A
Solon, OH 44139

October 4, 2018

Re: K173076
Trade/Device Name: CURA 16; ScintCare CT16
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: September 28, 2017
Received: September 29, 2017

Dear Paul McFeely:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K173076

Device Name
CURA CT16
ScintCare CT16

Indications for Use *(Describe)*
The CURA CT16/ScintCare CT16 is a Computed Tomography X-Ray System that is intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data collected at different angles and planes. The system may include signal analysis and display equipment, patient and equipment supports, components and accessories. The system is suitable for all patients.

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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Section 5 - 510(k) Summary

510(k) Submitter: FMI Medical Systems Inc.,
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Email: Scott.LeMaster@fmimaging.com

Company Contact: Scott LeMaster, Executive Vice President

Date of Submission: September 13, 2018

510(k) Preparer: Paul McFeely
Quality Assurance Engineer
FMI Medical Systems Inc.
29001 Solon Road, Unit A, Solon, Ohio 44139
Phone: 440-600-5952
Email: Paul.McFeely@fmimaging.com

Device Classification:

Device Name:	CURA CT16, ScintCare CT16
Regulation Name:	Computed tomography x-ray system
Review Panel:	Radiology
Product Code:	JAK
Regulation Number:	21 CFR 892.1750
Device Class:	2

Predicate Device:

Predicate Device:	SOMATOM Emotion 16
Predicate 510(k):	K151752
Regulation:	21 CFR 892.1750
Regulation Name:	Computed tomography x-ray system
Class:	II
Product Code:	JAK
Panel:	Radiology
Manufacturer:	Siemens Medical Solutions USA, Inc.

Device Description:

The CURA CT16/ScintCare CT16 computed tomography (CT) scanner is a medical imaging device utilizing X-ray computed tomography to obtain images of the entire body. The CURA CT16/ScintCare CT16 is a high performance imaging system that uses retina Solid State Detector technology to ensure high image quality. It uses ultrafast scintillator technology and application optimized algorithm to enhance image details and integrated anti-scatter grid (ASG) and A/D technology (ASIC) to maximize SNR. It produces better image quality by innovative calibration algorithms. Efficient design of the gantry helps achieve

structural stability under high G-Load and optimize the air flow to guarantee long thermal stability for wide range of ambient temperature and pleasant user experience.

The primary components of this system include the gantry, patient table, operator console and power distribution unit. Patient images are acquired, through the use of both hardware and software, via a rotating X-ray tube and detector array on the opposite side. The collected data is transmitted to the operator console for reconstruction into cross-sectional images.

The CURA CT16/ScintCare CT16 is designed for use in a controlled clinical setting, to collect X-ray images that aid in the diagnosis and treatment of various medical conditions by a physician or similarly licensed medical professional. The CURA CT16/ScintCare CT16 is intended for use by an appropriately trained or licensed professional, such as a physician, CT X-ray technician, or field service engineer. This device is restricted to sale by or on the order of a physician or similarly licensed medical professional (i.e. by prescription only).

The CURA CT16/ScintCare CT16 system is a stationary full gantry device. The gantry is comprised of several subsystems, including the X-ray tube, pre-patient collimator, detector array, cooling fans, power distribution unit, high voltage inverter, high voltage generator, data collection board (DCB) electronics and support electronics. The gantry is organized into two distinct sections, the stator (stationary elements) and the rotor (rotating elements). Slip rings are utilized to facilitate the transfer of electrical power and data between the gantry rotor and stator.

The CURA CT16/ScintCare CT16 system software implements many of the functions of the CURA CT16/ScintCare CT16 Whole Body system scanner. Among the functions performed by the software are:

- Entering and editing protocol, patient, and scan parameter data
- Initiating scans, executing scan protocols, monitoring status, and responding to faults
- Collecting image data and generating image views
- Image viewing (3d reconstruction, MPR, CPR, MIP)
- Image analysis (ROI)
- Reporting and image filming
- Exporting data for external viewing or printing
- Performing calibrations
- Performing diagnostics
- Metal artifact reduction is a capability of the system software, but is currently a future option.
- Iterative reconstruction is a capability of the system software, but is currently a future option.
- Dose modulation feature (imA) is a capability of the system software, but is currently a future option.

Device Safety and Risk Management:

The CURA CT16/ScintCare CT16 system device safety and risk management activities are documented in an associated Risk Management Plan. This document defines that the system complies with the following safety standards:

- IEC 60601-1, Medical electrical equipment
- IEC 60601-1-2, 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, 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, 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, Safety of laser products - Part 1: Equipment classification and requirements
- IEC 61223-3-5, Evaluation and routine testing in medical imaging departments - Part 3-5: Acceptance tests - Imaging performance of computed tomography X-ray equipment
- IEC 62366-1, Medical devices -- Part 1: Application of usability engineering to medical devices

The Risk Management Plan has also documented the assessment of risk utilizing ISO standard ISO 14971:2012, Application of Risk Management to Medical Devices. The CURA CT16/ScintCare CT16 system has been assessed and evaluated for risk, via defined Criteria for Risk Acceptability, through an approved Risk Management Matrix.

The following reference standards and guidance documents were utilized in the design and development of the CURA CT16/ScintCare CT16 system:

- ISO 14971:2012, Medical devices. Application of risk management to medical devices
- ISO 13485:2016, Application of quality management system for the design and manufacture of medical devices
- 21 CFR 820, Quality System Regulation
- 21 CFR 1020.33, Computed Tomography Equipment
- 21 CFR 1040.10, Laser Products (IEC 60825-1)
- 21 CFR 1020.30, Performance Standard for Diagnostic X-Ray Systems
- IEC 62304, Medical Device Software – Software life cycle processes

In addition, the CURA CT16/ScintCare CT16 system software documentation has been submitted according to a moderate level of concern utilizing the FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (issued 05/11/05).

Performance Testing:

The CURA CT16/ScintCare CT16 system was tested to ensure it functions as intended throughout the design process. The executed test documents were reviewed for accuracy and appropriateness as part of the design of the system. Additionally, evidence of dosimetric testing has been provided within this submission and was performed to ensure the allowable limits set forth by FMI Medical Systems are accurate and achievable by the system. Sample clinical images have been provided within the submission. The image quality has been evaluated by a certified radiologist.

Indications for Use:

The CURA CT16/ScintCare CT16 is a Computed Tomography X-Ray System that is intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data collected at different angles and planes. The system may include signal analysis and display equipment, patient and equipment supports, components and accessories. The system is suitable for all patients.

Substantial Equivalence:

FMI Medical Systems Inc. is citing substantial equivalence of the CURA CT16/ScintCare CT16 System to the 510(k), K151752, Predicate Device Siemens SOMATOM Emotion 16.

Substantial Equivalence Statement:

FMI Medical Systems Inc. is citing substantial equivalence of the CURA CT16/ScintCare CT16 System to the Siemens SOMATOM Emotion 16. Regulatory citations for the SOMATOM Emotion 16 are as follows:

Predicate Device: SOMATOM Emotion 16
Predicate 510(k): K151752
Regulation: 21 CFR 892.1750
Class: II
Product Code: JAK
Panel: Radiology
Manufacturer: Siemens Medical Solutions USA, Inc.

The CURA CT16/ScintCare CT16 System is substantially equivalent in design, intended use, indications for use and technology with the currently marketed predicate. There are no significant differences in materials, energy source, or technological characteristics. Both the proposed system and the predicate are computed tomography scanners that support visualization and evaluation tools. The design and fundamental scientific technology of both systems compare favorably.

The CURA CT16/ScintCare CT16 System and the predicate both produce images of the head and body by computer reconstruction of X-ray transmission data. The subsystems (patient supports, generator, x-ray tube and detector) of both devices compare favorably, with only minor differences that do not affect safety and efficacy. This is supported by a comparison of system component characteristics and specifications in the table above.

The CURA CT16/ScintCare CT16 System is as safe and effective as the predicate device, as demonstrated by successful completion of verification and validation testing, risk management activities and conformance to international standards. It is the conclusion of FMI Medical Systems that the CURA CT16/ScintCare CT16 System is substantially equivalent to the predicate, Siemens SOMATOM Emotion 16, and that there are no significant differences that raise new issues of safety or efficacy.

Additional comparisons are listed in the table below.

Characteristics – Components / Specifications	Predicate: Siemens SOMATOM Emotion 16	Proposed: CURA CT16/ScintCare CT16	Comments
Indications for use	The SOMATOM Emotion 6/16 systems are intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes* taken at different angles. (*spiral planes: the axial planes resulted from the continuous rotation of detectors and x-ray tube, and the simultaneous translation of the patient.)	The CURA CT16/ScintCare CT16 is a Computed Tomography X-Ray System that is intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data collected at different angles and planes. The system may include signal analysis and display equipment, patient and equipment supports, components and accessories. The system is suitable for all patients.	The CURA CT16/ScintCare CT16 proposed indications for use are consistent with the predicate. Both systems are capable of imaging in axial and spiral planes, at multiple angles. The CURA CT16/ScintCare CT16 also indicates the potential for signal analysis and display equipment, patient and equipment supports, components and accessories. In addition, the CURA CT16/ScintCare CT16 system specifies suitability for all patients.
Design			
Scan modes	Surview (scout) Helical Axial	Scout (surview) Helical Axial Multi-Axial	Compares favorably
Gantry			
Gantry aperture (bore) size	70 cm	70 cm	Compares favorably
Gantry tilt	+/- 30 degrees	+/- 30 degrees	Compares favorably
Patient Support / Couch / Table			
Patient supports	Included	Included	Compares favorably
Patient table scan range	160 cm (1600 mm)	1700 mm (170 cm)	The CURA CT16/ScintCare CT16 patient table scan range is 10 cm longer than the predicate. This difference does not affect safety or efficacy.
Generator power rating	50 kW	50 kW	Compares favorably
kVp settings	80, 110, 130 kV	80, 100, 120, 140 kV	kVp settings for CURA CT16/ScintCare CT16 (ranges from 80 to 140 kVp) are similar to the predicate (ranges from 80 to 130 kVp). For CURA CT16/ScintCare CT16, 1 of the 4 specific settings (80 kVp) is identical to the predicate. This does not affect safety or efficacy.

Characteristics – Components / Specifications	Predicate: Siemens SOMATOM Emotion 16	Proposed: CURA CT16/ScintCare CT16	Comments
mA range (step size)	20-345 mA (1 mA steps)	10 – 420 mA (10 mA steps)	The mA range for the CURA CT16/ScintCare CT16 (10 – 420 mA) is greater than the predicate (20 – 345 mA). Also, the step size of the CURA CT16/ScintCare CT16 (10 mA) is greater than that of the predicate (1 mA). These differences do not affect safety or efficacy.
Focal spot size	0.8 x 0.5 mm 0.8 x 0.7 mm	0.7 mm x 1.2 mm (small) 1.2 mm x 1.2 mm (large)	The focal spot sizes for the CURA CT16/ScintCare CT16 are greater than those of the predicate. This difference does not affect safety or efficacy.
Anode effective heat capacity	5 MHU	5.3 MHU	Anode effective heat capacity of the CURA CT16/ScintCare CT16 is 0.3 MHU greater than the predicate. This difference does not affect safety or efficacy.
X-ray tube, maximum applied power	345 mA	420 mA	X-ray tube maximum applied power for the CURA CT16/ScintCare CT16 is 75 mA greater than the predicate. This difference does not affect safety or efficacy.
Detector (DMS or Data Management System)			
Detectors	Solid state array, ultra-fast ceramic (UFC)	Solid-state ultra-high speed rare earth ceramic scintillator	Compares favorably
Slices	16 slices	16 slices	Compares favorably
Coverage	Maximum 1500 mm	Maximum 1700 mm	Coverage for the CURA CT16/ScintCare CT16 is 200 mm greater than the predicate. This difference does not affect safety or efficacy.