FMI Medical Systems, Inc.
% Dazhuang Meng
Senior Director of Product Development
29001 Solon Road, Unit A
SOLON OH 44139

March 5, 2020

Re: K192590
Trade/Device Name: CURA 778
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: November 5, 2019
Received: January 21, 2020

Dear Dazhuang Meng:

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)*
K192590

Device Name
CURA 778

Indications for Use *(Describe)*
The CURA 778 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 CURA 778 scanner is a whole body scanner, with cardiac and vascular X-ray Computed Tomography applications in patients of all ages.

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

K192590

510(k) Submitter: FMI Medical Systems Inc.
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Company Contact: Dazhuang Meng, Senior Director of Product Development

510(k) Preparer: FMI Medical Systems Inc.
29001 Solon Road, Unit A,
Solon, Ohio 44139, USA
Phone: +1 440-600-5952
Email: dazhuang.meng@fmimedical.com

Device Classification:

Device Name:	CURA 778
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:	Philips Ingenuity CT
Predicate 510(k):	K160743
Regulation:	21 CFR 892.1750
Regulation Name:	Computed tomography x-ray system
Class:	II
Product Code:	JAK
Panel:	Radiology
Manufacturer:	Philips Medical Systems (Cleveland), Inc.

Device Description:

The CURA 778 scanner is a medical imaging device utilizing X-ray computed tomography (CT) to obtain images of the entire body. The CURA 778 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 778 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 778 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 778 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 778 system software implements many of the functions of the CURA 778 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
- Dose modulation feature (imA)
- Integrate a 3rd party device for cardiac image processing, CREALIFE Anythink PACS Workstation, K131299 (510(k) number).

Device Safety and Risk Management:

The CURA 778 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 778 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 778 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 778 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 778 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 778 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 CURA 778 scanner is a whole body scanner, with cardiac and vascular X-ray Computed Tomography applications in patients of all ages.

Substantial Equivalence:

FMI Medical Systems Inc. is citing substantial equivalence of the CURA 778 system to the 510(k), K160743, predicate device Philips Ingenuity CT. Second substantial equivalence to the 510(k), K173076, predicate device CURA 16.

Substantial Equivalence Statement:

FMI Medical Systems Inc. is citing substantial equivalence of the CURA 778 System to the Philips Ingenuity CT. Regulatory citations for the Philips Ingenuity CT are as follows:

Predicate Device:	Philips Ingenuity CT
Predicate 510(k):	K160743
Regulation:	21 CFR 892.1750
Class:	II
Product Code:	JAK
Panel:	Radiology
Manufacturer:	Philips Medical Systems (Cleveland), Inc.

The CURA 778 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 778 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 778 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 778 System is substantially equivalent to the predicate, Philips Ingenuity CT, 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: Ingenuity CT	Proposed: CURA 778	Comments
Indications for use	The Ingenuity CT is a Computed Tomography X-Ray System intended to produce images of the head and body by computer reconstruction of x-ray transmission data taken at different angles and planes. These devices may include signal analysis and display equipment, patient and equipment supports, components and accessories. The Ingenuity CT is indicated for head, whole body, cardiac and vascular X-ray Computed Tomography applications in patients of all ages. These scanners are intended to be used for diagnostic imaging and for low dose CT lung cancer	The CURA 778 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 CURA 778 scanner is a whole body scanner, with cardiac and vascular X-ray Computed Tomography applications in patients of all ages.	The CURA 778 proposed indications for use are consistent with the predicate. Both systems are capable of imaging in axial and spiral planes, at multiple angles. Indicates the potential for signal analysis and display equipment, patient and equipment supports, components and accessories. Whole body scanner, with cardiac and vascular X-ray Computed Tomography applications in patients of all ages. Difference is that Philips Ingenuity has low dose CT lung cancer screening feature.
Design			
Application	Head / body	Full body (includes head)	Compares favorably
Scan regimen	Continuous rotation	Continuous rotation	Compares favorably
Scan modes	Surview (Scout) Helical Scan Axial Scan	Scout (Surview) Helical Axial Multi-Axial(Step and Shoot)	Compares favorably
Gantry			
Gantry aperture (bore) size	70 cm	70 cm	Compares favorably
Gantry tilt	+/-30 degrees	+/-30 degrees	Compares favorably
Focus – isocenter distance	570mm	558 mm	Isocenter distance for CURA 778 is 12 mm smaller than the predicate. This difference does not affect safety or efficacy.
Focus – detector distance	1040 mm	950.25 mm	Detector distance for the CURA 778 is 89.75 mm smaller than the predicate. This difference does not affect safety or efficacy.
Rotation times	0.4,0.5, 0.75, 1, 1.5,2.0 seconds	0.39, 0.5, 0.75, 1.0, 1.5, 2.0 seconds	Rotation time capability for CURA 778 (ranges from 0.39

Characteristics – Components / Specifications	Predicate: Ingenuity CT	Proposed: CURA 778	Comments
			to 2.0 seconds) is similar to the predicate (ranges from 0.4 to 2.0 seconds). For CURA 778, 5 out of 6 specific settings (0.5, 0.75, 1.0, 1.5, and 2.0 seconds) are identical to the predicate. This does not affect safety or efficacy.
Patient Support / Couch / Table			
Patient supports	Included	Included	Compares favorably
Patient table scan range	2000 mm	1700 mm	The patient table scan range is 300 mm shorter than the predicate. This difference does not affect safety or efficacy.
Table Z-position accuracy	+/- 0.25 mm	+/- 0.25 mm	Compares favorably
Table longitudinal speed	1 to 100 mm / second	Up to 200 mm / second	The maximum speed capability of the CURA 778 is 100 mm/sec greater than the predicate. This difference does not affect safety or efficacy.
Table maximum load capacity	204 kg	205 kg	Table load capacities are similar. The table supports 1 additional kilograms compared to the predicate. This difference does not impact safety or efficacy.
Generator			
Generator power rating	80 kW	80 kW	Compares favorably
kVp settings	80, 100, 120, 140 kV	80, 100, 120, 140 kV	Compares favorably
mA range (step size)	20-665 mA (1 mA steps)	10 – 660 mA (10 mA steps)	The mA range for the CURA 778 (10 – 660 mA) is similar than the predicate (20 – 665 mA). Also, the step size of the CURA 778 (10 mA) is greater than that of the predicate (1 mA). These differences do not affect safety or efficacy.
X ray tube			

Characteristics – Components / Specifications	Predicate: Ingenuity CT	Proposed: CURA 778	Comments
Focal spot size	0.5 x 1.0 mm 1.0 x 1.0 mm	0.6 mm x 1.2 mm (small) 1.1 mm x 1.2 mm (large)	The focal spot sizes for the CURA 778 are greater than those of the predicate. This difference does not affect safety or efficacy.
Anode effective heat capacity	8.0 MHU	8.0 MHU	Compares favorably
X-ray tube, maximum applied power	665 mA	660 mA	X-ray tube maximum applied power for the CURA 778 is 5 mA smaller than the predicate. This difference does not affect safety or efficacy.
Detector (DMS or Data Management System)			
Detectors	Solid-state GOS	Solid-state GOS	Compares favorably
Slices	128 slices	128 slices	Compares favorably
Coverage	40 mm	40 mm	Compares favorably
Slice thickness (mm) (image reconstruction)	0.5mm-12.5mm	0.5 mm 0.625 mm 1.25 mm 2.5 mm 5 mm 10 mm	For reconstruction of axial images, the range of and number of options for slice thickness are similar between the CURA 778 and the predicate. Multiple options provide the user with the ability to select parameters that support required image quality and capture the target area of interest. The differences do not affect safety or efficacy.
Slice thickness (mm) (image reconstruction)	0.55 mm-5mm	0.5 mm 0.625 mm 1mm 1.25 mm 2mm 2.5 mm 3mm 4mm 5 mm 6mm 7mm 8mm 9mm 10 mm	For reconstruction of helical images, the range of and number of options for slice thickness are similar between the CURA 778 and the predicate. Multiple options provide the user with the ability to select parameters that support required image quality and capture the target area of interest. The differences do not affect safety or efficacy.

Characteristics – Components / Specifications	Predicate: Ingenuity CT	Proposed: CURA 778	Comments
Scan field	250 mm, 500 mm	250 mm, 500 mm	Compares favorably
Image matrix	512 x 512 768 x 768 1,024 x 1,024	512 x 512 1,024 x 1,024 (Optional)	The image matrix of the CURA 778 is less than the predicate. This difference does not affect safety or efficacy.

FMI Medical Systems Inc. is citing second substantial equivalence of the CURA 778 system to the CURA 16. Regulatory citations for the CURA 16 are as follows:

Predicate Device: CURA 16
Predicate 510(k): K173076
Regulation: 21 CFR 892.1750
Class: II
Product Code: JAK
Panel: Radiology
Manufacturer: FMI Medical Systems, Inc.

The CURA 778 system is substantially equivalent (with some enhancement) in design, intended use, indications for use and technology with the currently marketed predicate. There are no significant differences in materials, 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, except the energy source, detector coverage. On CURA 778, the energy source has bigger capacity, and the detector has larger coverage, which enable more patient through output, lower dose, and advanced features (for example: cardiac, vascular, … …)

The submission K192590 CURA 778 CT scanner device, is based on the mechanical and control system architecture of the previous one (CURA 16, K173076), with below enhancement:

	CURA 16	CURA 778	
Tube and generator	5.3MHU	8MHU	Enhanced
Flying focal spot (Z direction)	No	Yes	Enhanced
Detector physical slices	16	64	Enhanced
Detector coverage (mm)	18.56	40	Enhanced
Rotation speed (second/rotation)	0.5	0.39	Enhanced
Motion control system			Same
Mechanical structure			Same
Software and Recon architecture			Same
Cardiac application	No	Yes	Enhanced

The CURA 778 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 comparable or has similar architecture/structure/technology behind them, 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 CURA778 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 778 system is substantially equivalent (with some enhancement) to the predicate, CURA 16, and 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: CURA 16**	**Proposed: CURA 778**	**Comments**
Indications for use	The 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 778 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 CURA 778 scanner is a whole body scanner, with cardiac and vascular X-ray Computed Tomography applications in patients of all ages.	The CURA 778 proposed indications for use are consistent with the predicate. Both systems are capable of imaging in axial and spiral planes, at multiple angles. Indicates the potential for signal analysis and display equipment, patient and equipment supports, components and accessories. In addition, the CURA 778 is also indicated for cardiac and vascular X-ray Computed Tomography applications in patients of all ages.
Design			
Application	Full body(includes head)	Full body (includes head)	Compares favorably
Scan regimen	Continuous rotation	Continuous rotation	Compares favorably
Scan modes	Scout(Surview) Helical Axial Multi-Axial	Scout (Surview) Helical Axial Multi-Axial(Step and Shoot)	Compares favorably
Gantry			
Gantry aperture (bore) size	70 cm	70 cm	Compares favorably
Gantry tilt	+/-30 degrees	+/-30 degrees	Compares favorably
Focus –	558mm	558 mm	Compares favorably

Characteristics – Components / Specifications	Predicate: CURA 16	Proposed: CURA 778	Comments
isocenter distance			
Focus – detector distance	948.40 mm	950.25 mm	Detector distance for the CURA 778 is 1.58 mm length than the predicate. This difference does not affect safety or efficacy.
Rotation times	0.5, 0.75, 1.0, 1.5, 2.0 seconds	0.39, 0.5, 0.75, 1.0, 1.5, 2.0 seconds	Rotation time capability for CURA 778, 5 out of 6 specific settings (0.5, 0.75, 1.0, 1.5, and 2.0 seconds) are identical to the predicate. 0.39 second is the enhancement for this 64 row/128 slices machine. This does not affect safety or efficacy.
Patient Support / Couch / Table			
Patient supports	Included	Included	Compares favorably
Patient table scan range	1700 mm	1700 mm	Compares favorably
Table Z-position accuracy	+/- 0.25 mm	+/- 0.25 mm	Compares favorably
Table longitudinal speed	1 to 150 mm / second	Up to 200 mm / second	The maximum speed capability of the CURA 778 is 50 mm/sec greater than the predicate. This difference does not affect safety or efficacy.
Table maximum load capacity	205 kg	205 kg	Compares favorably
Generator			
Generator power rating	50 kW	80 kW	Compares favorably
kVp settings	80, 110,130 kV	80, 100, 120, 140 kV	CURA 778 as similar kV setting compare with CURA 16. This difference does not affect safety or efficacy.
mA range (step size)	10-420 mA (10 mA steps)	10 – 660 mA (10 mA steps)	The mA range for the CURA 778 (10 – 660 mA) is bigger than the predicate (10 – 420 mA), while has the same step size (10 mA). Bigger range enable more patients scan capacity and

Characteristics – Components / Specifications	Predicate: CURA 16	Proposed: CURA 778	Comments
			some specific application protocols. These differences do not affect safety or efficacy.
X ray tube			
Focal spot size	0.7 x 1.2 mm (small) 1.2 x 1.2 mm (large)	0.6 mm x 1.2 mm (small) 1.1 mm x 1.2 mm (large)	The focal spot sizes for the CURA 778 specs are smaller than those of the predicate. This difference does not affect safety or efficacy.
Anode effective heat capacity	5.3 MHU	8.0 MHU	CURA 778 is bigger than the predicate. Bigger heat capacity enable more patients scan possibility and some specific application protocols. These differences do not affect safety or efficacy.
X-ray tube, maximum applied power	420 mA	660 mA	X-ray tube maximum applied power for the CURA 778 is 240 mA bigger than the predicate. This difference does not affect safety or efficacy.
Detector (DMS or Data Management System)			
Detectors	Solid-state ultra-high speed rare earth ceramic scintillator	Solid-state GOS	Compares favorably
Slices	16 slices	128 slices	CURA 778 is a 128 slices product, while CURA 16 is a 16 slices one. This difference does not affect safety. 128 slices can have more features, for example cardiac.
Coverage	Maximum 18.56 mm	Maximum 40 mm	Coverage for the CURA 778 is 21.44 mm wider than the predicate. This difference does not affect safety. With bigger coverage detector, product can have more features, for example cardiac.
Axial Slice thickness (mm) (image reconstruction)	0.58 mm 1.16 mm 2.32 mm 4.64 mm 9.28 mm 18.56 mm	0.5 mm 0.625 mm 1.25 mm 2.5 mm 5 mm 10 mm	For reconstruction of axial images, the range of and number of options for slice thickness are similar between the CURA 778 and the predicate. Multiple options

Characteristics – Components / Specifications	Predicate: CURA 16	Proposed: CURA 778	Comments
			provide the user with the ability to select parameters that support required image quality and capture the target area of interest. The differences do not affect safety or efficacy.
Helical Slice thickness (mm) (image reconstruction)	0.5 mm 1.0 mm 1.5 mm 2.0 mm 2.5 mm 3.0 mm 4.0 mm 5.0 mm 6.0 mm 7.0 mm 8.0 mm 9.0 mm 10.0 mm	0.5 mm 0.625 mm 1mm 1.25 mm 2mm 2.5 mm 3mm 4mm 5 mm 6mm 7mm 8mm 9mm 10 mm	For reconstruction of helical images, the range of and number of options for slice thickness are similar between the CURA 778 and the predicate. Multiple options provide the user with the ability to select parameters that support required image quality and capture the target area of interest. The differences do not affect safety or efficacy.
Scan field	500 mm	250 mm, 500 mm	Compares favorably
Image matrix	512 x 512	512 x 512 1,024 x 1,024 (Optional)	The image matrix of the CURA 778 has more option than the predicate. This difference does not affect safety or efficacy.