Analogic Corporation
% Ms. Karen Provencher
Sr. Regulatory Affairs Specialist
8 Centennial Drive
PEABODY MA 01960

February 13, 2018

Re: K172058
Trade/Device Name: CT6485, CT12885
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: January 29, 2018
Received: January 30, 2018

Dear Ms. Provencher:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 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)*
K172058

Device Name
CT6485, CT12885

Indications for Use *(Describe)*
The Analogic CTXX85 systems are intended to produce images of the head and body by computer reconstruction of x-ray transmission data taken at different angles and planes. The CTXX85 systems are indicated for pediatric and adult 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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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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Date Prepared: January 29, 2018

II. Device Names / Common Names / Classification Names:

Trade Name:	CT6485, CT12885
Common Name:	Computed Tomography (CT) Scanner
Classification Name:	Computed Tomography X-Ray System
Product Code:	JAK
Class:	II
Regulation Number:	21 CFR §892.1750
Classification Panel:	Radiology

III. Identification of Predicate or Legally Marketed Devices:

The predicate devices are Class II per 21 CFR §892.1750, with product code JAK:
Siemens Somatom Definition AS - K103127 (03/04/2011)
Siemens Somatom Definition Edge - K120579 (05/23/2012)

IV. Device Description:

The CTXX85 is a whole-body, multi-slice CT scanner platform that enables multiple configurations for diagnostic imaging. The systems produce images and calculations that are intended for use by competent medical personnel as part of a clinical diagnosis. There are two models of the CTXX85 scanner: CT6485 (64 slice configuration) and CT12885 (128 slice configuration).

The CTXX85 CT Scanners includes LISA (Low-dose Iterative noise reduction Solution by Analogic), an advanced algorithm which reduces image noise while maintaining (or improving) spatial resolution.

The following main subsystems make up the scanner platforms: tilting gantry (X-ray tube, X-ray generator, X-ray beam collimator), data management system (detector array, electronics), patient table with accessories, power distribution unit, and operator console (touchscreen user interface computer, gantry control box).

Accessories for the CT scanners include: patient table CT slicker cushion, head holder, foot extension board, wedge knee pad, patient restraints, IV pole and holder and QA phantom and mount.

V. Indications / Intended Use:

The Analogic CTXX85 systems are intended to produce images of the head and body by computer reconstruction of x-ray transmission data taken at different angles and planes. The CTXX85 systems are indicated for pediatric and adult patients.

VI. Comparison of Technological Characteristics with the Predicate Device:

Summary of Similarities

The indication for use and intended use of the proposed CTXX85 CT Scanners are equivalent to the predicate device scanners Siemens Somatom Definition AS and Somatom Definition Edge.

The overall system technology and principles of operation are equivalent.

The performance results of scanning and image reconstruction is comparable as demonstrated in verification and validation testing.

The following list of features are available in all proposed and predicate systems: radiation dose control, in room start, remote gantry tilt, rear gantry keypads, adaptive filtration for noise reduction, spiral scanning, artifact reduction algorithms, slice doubling, DICOM, MPR (multi-planar reconstruction), MIP/MinIP (maximum/minimum intensity projection), 3D shaded surface display, 3D volume rendering, bolus trigger, iterative

reconstruction, Cardiac Imaging with Gated ECG Monitor and CT Angiography.

Summary of Differences

The differences between the proposed CTXX85 CT Systems and the predicate devices are in the design of the subsystems. The resulting effect of these differences do not impact the performance or image quality as demonstrated in verification and validation testing. The differences in design are summarized below:

- Gantry Design – The proposed and predicate devices have gantry designs with an x-ray tube fixed opposite from the detector that rotates around the patient. The difference between the proposed systems and the predicate device is in the operation of the electromechanical components that allow the transfer of power and data from the stationary to rotating structure.
- Gantry & Table Design - The overall dimensions, weight and gantry aperture are different in the proposed devices.
- Method for slice doubling – the proposed CTXX85 CT Scanners use a reconstruction software approach while the predicate device uses X-ray tube focal spot deflection to produce a similar effect.
- X-Ray Tube – the methods for heat dissipation are different.

VII. Performance Data:

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

Non-clinical Test / Performance Testing - Bench:

Bench testing was performed and the CTXX85 scanners fulfilled the requirements of the following FDA consensus standards and performance requirements for 21CFR §1020.30, §1020.33 which are applicable to Computed Tomography X-Ray Systems, 21 CFR §892.1750:

IEC61223-2-6 - Evaluation & Routine Testing in Medical Imaging Departments - Part 2-6: Constancy Tests - Imaging Performance of Computed Tomography X-Ray Equipment

IEC61223-3-5 - Medical Electrical Equipment - Part 2-44: Particular Requirements for the Basic Safety and Essential Performance of X-Ray Equipment for Computed Tomography

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

NEMA PS 3.1 - 3.20 - Digital Imaging & Communications in Medicine (DICOM) Set

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

NEMA XR 25 - Computed Tomography Dose Check

NEMA XR 28 - Supplemental Requirements for User Information and System Function Related to Dose in CT

IEEE Std. 3333.2.1 - IEEE Recommended Practice for Three Dimensional Medical Modeling

IEC 62366 - Consolidated version medical devices - application of usability engineering to medical devices

IEC 60825 - Safety of laser products - Part 1: Equipment classification and requirements

Image Quality performance testing for the CTXX85 was conducted on standard phantom models to assess modulation transfer function (MTF), low contrast detectability, noise, CT number accuracy, CT uniformity, axial slice thickness, helical slice sensitivity profile, axial and helical image quality for head and body.

Testing to the above-mentioned standards were performed on the proposed CTXX85 devices. Additionally, testing was conducted to evaluate image quality performance of the iterative reconstruction algorithm. The results of these tests demonstrate that the proposed device performs as intended. The result of all conducted testing was found acceptable to support the claim of substantial equivalence.

Biocompatibility:

The main CTXX85 units are not patient contacting. However, there are several system accessories (patient table CT slicker cushion, head holder, wedge knee pad, table top and patient restraints) which are patient contacting and categorized per Section 5.2 and Table A1 of AAMI/ANSI/ISO 10993-1 as Surface Contact: Skin, Duration: Limited <24hr. The patient contacting accessories comply with the biocompatibility standard requirements.

Sterilization:
There are no sterilization requirements associated with the CTXX85 CT Scanners.

Electrical Safety & Electromagnetic Compatibility (EMC):
Electrical safety testing is compliant with the following standards:

- AAMI/ANSI/ES 60601-1: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility - Requirements and tests

Software Verification and Validation Testing:
Software verification and validation testing were conducted and documentation was provided as recommended by the FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern. The CTXX85 CT Scanner complies with EN IEC 62304 Medical Device Software Life-Cycle Processes. The submission contains performance data which demonstrates conformance to special controls for medical devices containing software.

Animal Testing:
Not applicable – animal testing was not required to support substantial equivalence to the predicate device.

Clinical Studies:

Sample clinical images of the brain, chest, abdomen and extremity, reconstructed via FBP and LISA with different strengths were evaluated by a board-certified radiologist to confirm that the images were of diagnostic quality.

VIII. Conclusion:

The proposed CTXX85 CT Scanners are substantially equivalent to the predicate Siemens Somatom Definition AS and Somatom Definition Edge CT Scanners (K103127 and K120579). The differences between the proposed and predicate devices do not impact the safety and effectiveness of the proposed device. Performance testing presented in the submission supports that the proposed device is substantially equivalent to the legally marketed predicate devices.