September 7, 2018

Analogic Corporation
Karen Provencher
Sr. Regulatory Affairs Specialist
8 Centennial Drive
PEABODY, MASSACHUSETTS 01960

Re: K182147
Trade/Device Name: CTXX85
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: August 7, 2018
Received: August 8, 2018

Dear Karen 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. 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); 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,

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)*
K182147

Device Name
CTXX85

Indications for Use *(Describe)*
The Analogic CTXX85 CT Scanner 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 CT Scanner 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K182147 - 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

I. Submitter:

Analogic Corporation
8 Centennial Drive
Peabody, MA 01960

Tel: (978) 326-4668
Fax: (978) 977-6808
Contact: Karen Provencher
Sr. Regulatory Affairs Specialist
E-mail: kprovencher@analogic.com

Date Prepared: August 7, 2018

II. Device Names / Common Names / Classification Names:

Trade Name:	CTXX85
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 device is Class II per 21 CFR §892.1750, with product code JAK: Analogic CTXX85 CT Scanner – K172058 (2-13-2018)

IV. Device Description:

The CTXX85 CT Scanner 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 three (3) models of the CTXX85 CT Scanner: CT1685 (16 slice configuration), 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 CT Scanner 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 CT Scanner 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 new proposed CTXX85 scanner model is the same as the predicate CTXX85 scanners.

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.

Summary of Differences

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

- Predicate device models CT6485, CT12885; Proposed new model CT1685

- Detector – CT1685 has a 16 row DMS (data management system) with 20 mm axial coverage; CT6485/CT12885 has a 64 row DMS with 40 mm axial coverage.
- X-Ray Tube – CT1685 has an x-ray tube with smaller heat storage, compared to CT6485/CT12885.
- Slice configuration – CT1685 has 16 slices, CT6485 has 64 slices, CT12885 has 128 slices.
- CT1685 has a slower maximum gantry rotation speed, compared to CT6485/CT12885.
- CT1685 does not support ECG-gated Cardiac scanning.
- CT1685 does not support Coronary Artery Calcium Scoring.

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 new scanner model CT1685 fulfills the requirements of the following FDA consensus standards and performance requirements for 21CFR §1020.30, §1020.33 which are applicable for 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 CT1685 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 was performed. 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.

The system accessories which are patient contacting did not change since the last submission K172058.

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

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 results 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 new proposed CT1685 model of the CTXX85 CT Scanner platform is substantially equivalent to the cleared models CT6485 and CT12885 of the CTXX85 CT Scanner platform (K172058). 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 new proposed device model is substantially equivalent to the legally marketed predicate devices.