Analogic Corporation
℅ Ms. Laura Green
Regulatory
8 Centennial Drive
PEABODY MA 01960

February 2, 2021

Re: K201231
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: December 21, 2020
Received: December 22, 2020

Dear Ms. Green:

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)*
K201231

Device Name
CTXX85

Indications for Use *(Describe)*
The 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 CTXXX85 CT scanner systems are indicated for head and whole-body X-ray Computed Tomography applications for both pediatric and adult patients. The images delivered by the system can be used by a trained physician and trained healthcare professionals as an aid in diagnosis, treatment preparation and radiation therapy planning.

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.

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

I. Submitter:

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Contact: Laura Green
Regulatory Affairs
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Date Prepared: April 24, 2020

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:

Predicate Device(s):
The primary predicate device is Class II per 21 CFR §892.1750, with product code JAK: K182147 - Analogic CTXX85 CT Scanner

The predicate has not been the subject of any design related recalls.

Reference Device:
The reference device is Class II per 21 CFR §892.1750, with product code JAK: K173607 - SOMATOM CT SCANNER SYSTEMS

IV. Device Description:

Analogic intends to market the Analogic CTXX85 CT Scanner with a new software version (version 1.3).

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 system is designed for routine radiological imaging procedures as well as advanced techniques such as coronary CT angiography, brain / organ perfusion, cardiac imaging with gated ECG, and CT-guided procedures.

The CTXX85 system is designed with LISA (Low-dose Iterative noise reduction Solution by Analogic), an advanced algorithm which reduces image noise while maintaining (or improving) spatial resolution and Iterative Bone Correction (IBC) in scan protocols associated with Head patient anatomy.

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, QA phantom and mount, CIVCO table overlay and cardiac trigger module (CTM).

V. Intended Use and Indications for Use:

The 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 CTXXX85 CT scanner systems are indicated for head and whole-body X-ray Computed Tomography applications for both pediatric and adult patients. The images delivered by the system can be used by a trained physician and trained healthcare professionals as an aid in diagnosis, treatment preparation and radiation therapy planning.

VI. Comparison of Technological Characteristics with the Predicate Device:

Analogic intends to market a new version of the Analogic CTXX85 with software version 1.3. The subject device is based on modifications to the legally marketed and commercially available Analogic CTXX85 Scanner platform (K182147).

The ***CTXX85 CT Scanners (software 1.3)*** provides the same technological characteristics in terms of materials, energy source, and control mechanisms when compared to the predicate device. The fundamental intended use, scientific technology and principles of operation remains unchanged from the predicate device.

The proposed subject device ***CTXX85 CT Scanner (software version 1.3)*** will support the following key modifications in comparison with the predicate device:

- Software-based algorithm to enable Metal Artifact Reduction (MAR) post-reconstruction protocol.
- Extended Field of View (FOV) algorithm.
- Enable cardiac imaging with gated ECG function on the CT1685 model (which currently exists in the CT6485 and CT12885 models).
- New optional cardiac trigger module accessory which provides triggers for ECG-gated scans.
- Option for use of CIVCO table overlay (K973842/K180021) for radiotherapy planning.
- Modified indication for use statement.

The software and hardware components have been modified or improved in comparison to the predicate device to support enhanced device functionality. The software has been updated to support additional features as well as provide minor updates for workflow, serviceability, and anomaly corrections as compared to the

predicate device. The hardware components of the subject device have been modified to include and integrate with a flat table overlay accessory and an integrated cardiac trigger module (CTM) accessory.

Any differences in technological characteristics do not raise different questions of safety and effectiveness. Verification and validation testing is complete. Test results show that the subject device is comparable to the predicate device in terms of technological characteristics and safety and effectiveness, and therefore is substantially equivalent to the predict device. Analogic believes that the subject device is substantially equivalent to the predicate device.

VII. Performance Data:

The Analogic ***CTXX85 CT Scanners (software 1.3)*** CTXX85 CT Scanner has been developed in accordance with the requirements of the following standards:

- IEC 62304 - Medical Device Software - Software Lifecycle Processes (Software / Informatics)
- IEC 62366 - Consolidated version medical devices - application of usability engineering to medical devices
- ISO 14971 Medical Devices - Applications of Risk Management to Medical Devices

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

Non-clinical Test/Performance Testing - Bench:

Non-clinical testing, including phantom tests, were conducted during product development. The modifications described in this Premarket Notification were supported with verification and validation testing.

Testing 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. Analogic claims conformance to the following performance standards:

- IEC 61223-2-6 - Evaluation & Routine Testing in Medical Imaging Departments - Part 2-6: Constancy Tests - Imaging Performance of Computed Tomography X-Ray Equipment
- IEC 61223-3-5 - Evaluation & Routine Testing in Medical Imaging Departments - Part 3-5: Imaging Performance of Computed Tomography X-Ray Equipment
- NEMA PS 3.1 - 3.20 - Digital Imaging & Communications in Medicine (DICOM) Set
- NEMA XR 25 - Computed Tomography Dose Check
- NEMA XR 28 - Supplemental Requirements for User Information and System Function Related to Dose in CT
- NEMA XR 29 - Standard Attributes on CT Equipment Related to Dose Optimization and Management
- 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

Electrical Safety and Electromagnetic Compatibility (EMC) testing were conducted in accordance 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 Disturbances - Requirements And Tests
- 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 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

In addition to testing to the above-mentioned standards, testing was conducted to evaluate image quality performance of the Metal

Artifact Reduction (MAR) algorithm. Testing for computed-tomography simulation scan process was also completed in accordance with AAPM TG-66 Appendix D "CT-Simulator Laser QA" and Appendix E "Scanner Table Tests

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. Theses system accessories did not change since the last submission (K182147) therefore, no additional biocompatibility testing was performed.

Biocompatibility testing for the CIVCO table overlay accessory is provided with the related submissions (K973842/K180021), as well as this submission.

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

Software Verification and Validation Testing:
Software verification and validation testing were completed 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.

Analogic conforms to the Cybersecurity requirements by implementing a process of preventing unauthorized access, modifications, misuse or denial of use, or the unauthorized use of

information that is stored, accessed, or transferred from a medical device to an external recipient.

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

Clinical Studies:

Not applicable – clinical studies were not required to support substantial equivalence to the predicate device.

General Safety and Effectiveness Concerns
The device labeling contains instructions for use as well as necessary cautions and warnings to provide for safe and effective use of the device. Risk management is ensured via a system related Risk analysis, which is used to identify potential hazards. These potential hazards are controlled during development, verification and validation testing according to the Risk Management process. In order to minimize electrical, mechanical, and radiation hazards, Analogic adheres to recognized and established industry practice and standards.

VIII. Conclusion:

The data included in this submission demonstrates that the Analogic ***CTXXX85 CT Scanner (software 1.3)*** perform comparably to the predicate device and supports a finding of substantial equivalence. The predicate device was cleared based on the results of non-clinical testing including verification and validation, conformance to standards and image quality tests. The subject device is also tested using the same methods as used for the predicate devices. The non-clinical data supports the safety of the device and the hardware and software verification and validation demonstrates that the subject device Analogic CTXXX85 CT Scanner performs as intended in the specified use conditions.