June 16, 2023

Siemens Medical Solutions USA Inc.
% Clayton Ginn
Regulatory Affairs Specialist
810 Innovation Drive
KNOXVILLE TN 37932

Re: K230421
Trade/Device Name: SOMATOM Edge Plus, SOMATOM Confidence, SOMATOM Definition Edge, SOMATOM Definition AS/AS+, SOMATOM Definition AS Open, SOMATOM Drive, SOMATOM Force, SOMATOM Definition Flash
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: May 16, 2023
Received: May 16, 2023

Dear Clayton Ginn:

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K230421

Device Name

SOMATOM Edge Plus;
SOMATOM Confidence;
SOMATOM Definition Edge;
SOMATOM Definition AS/AS+;
SOMATOM Definition AS Open;
SOMATOM Drive;
SOMATOM Force;
SOMATOM Definition Flash

Indications for Use *(Describe)*

This computed tomography system is intended to generate and process cross-sectional images of patients by computer reconstruction of x-ray transmission data.

The images delivered by the system can be used by trained staff as an aid in diagnosis, treatment and radiation therapy planning as well as for diagnostic and therapeutic interventions.

This CT system can be used for low dose lung cancer screening in high risk populations*.
*As defined by professional medical societies. Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information.

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 K230421

for

SOMATOM CT Scanner Systems – Software Version SOMARIS/7 *syngo* CT VB30

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

I. Contact Details

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Note: Description in this submission use the short company name Siemens. It covers both manufacturing locations and names as listed above. Brand name on all products is Siemens Healthineers.

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II. Device Name and Classification

Product Name	Trade Name
SOMATOM Edge Plus	SOMATOM Edge Plus
SOMATOM Confidence	SOMATOM Confidence
SOMATOM Definition Edge	SOMATOM Definition Edge
SOMATOM Definition AS/AS+	SOMATOM Definition AS/AS+
SOMATOM Definition AS Open	SOMATOM Definition AS Open
SOMATOM Drive	SOMATOM Drive
SOMATOM Force	SOMATOM Force
SOMATOM Definition Flash	SOMATOM Definition Flash

Common Name:	Computed tomography X-ray system
Classification Name:	System, X-Ray, Tomography, Computed
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK

III. Predicate Device

Trade Name:	SOMATOM CT Scanner Systems
510(k) Number:	K190578
Clearance Date:	June 27, 2019
Common Name:	Computed tomography X-ray system
Classification Name:	System, X-Ray, Tomography, Computed
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK
Recall Information:	All predicate device recalls have been considered in the subject device design.

IV. Device Description Summary

Siemens intends to market a new software version, SOMARIS/7 *syngo* CT VB30 for the following SOMATOM Computed Tomography (CT) Scanner Systems:

Single Source CT Systems:

- SOMATOM Definition AS/AS+
- SOMATOM Definition AS Open
- SOMATOM Definition Edge
- SOMATOM Confidence
- SOMATOM Edge Plus

Dual Source CT Systems:

- SOMATOM Force
- SOMATOM Drive
- SOMATOM Definition Flash

The subject device SOMATOM CT Scanner Systems with SOMARIS/7 *syngo* CT VB30 are Computed Tomography X-ray Systems which feature one (single source) or two (dual source) continuously rotating tube-detector system and function according to the fan beam principle. The SOMATOM CT Scanner Systems with Software SOMARIS/7 *syngo* CT VB30 produces CT images in DICOM format, which can be used by trained staff for post-processing applications commercially distributed by Siemens Healthcare and other vendors as an aid in diagnosis, treatment preparation and therapy planning support (including, but not limited to, Brachytherapy, Particle including Proton Therapy, External Beam Radiation Therapy, Surgery). The computer system delivered with the CT scanner is able to run optional post processing applications.

Only trained and qualified users, certified in accordance with country-specific regulations, are authorized to operate the system. For example, physicians, radiologists, or technologists. The user must have the necessary U.S. qualifications in order to diagnose or treat the patient with the use of the images delivered by the system.

The platform software for the SOMATOM CT Scanner Systems, SOMARIS/7 *syngo* CT VB30, is a command-based program used for patient management, data management, X-ray scan control, image reconstruction, and image archive/evaluation.

Software version *syngo* CT VB30 (SOMARIS/7 *syngo* CT VB30) is a modified software version of the predicate device, *syngo* CT VB20 (SOMARIS/7 *syngo* CT VB20) cleared in K190578.

Software version SOMARIS/7 *syngo* CT VB30 will be offered ex-factory and as an optional upgrade for the applicable existing SOMATOM CT Systems.

Compared to the predicate devices referenced within this submission, the subject devices support the following modifications:

1) New/Modified Hardware

- syngo Acquisition Workplace and syngo CT Workplace computer upgrades due to obsolescence of the predecessor.

2) Software version SOMARIS/7 syngo CT VB30 including the following new/modified features

- FAST Bolus update for individualized patient scan trigger.
- FAST 3D Camera update to to support adolescent patients in addition to adult patients
- FAST applications updates (FAST Spine, FAST Planning)
- Workflow improvements for FAST 4D
- Updated Automatic Patient Instructions
- Recon Jobs limit extended up to 18
- Additional kV setting for Tin Filtration
- Additional default exam scan protocols (e.g. abdomen protocols, Angio-CT, Dual Spiral Dual Energy and ECG gated Flash protocols with tin filtration at high kV)

The bundle approach is feasible for this submission since the subject devices have similar technological characteristics, software operating platform, and supported software characteristics. All subject devices will support previously cleared software and hardware features in addition to the applicable modifications as described within this submission. The intended use remains unchanged compared to the predicate devices.

V. Indications for Use

This computed tomography system is intended to generate and process cross-sectional images of patients by computer reconstruction of x-ray transmission data.
The images delivered by the system can be used by trained staff as an aid in diagnosis, treatment and radiation therapy planning as well as for diagnostic and therapeutic interventions.
This CT system can be used for low dose lung cancer screening in high risk populations.*
*As defined by professional medical societies. Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information.

VI. Indications for Use Comparison

Predicate Device Indications for Use:

This computed tomography system is intended to generate and process cross-sectional images of patients by computer reconstruction of x-ray transmission data.
The images delivered by the system can be used by a trained physician as an aid in diagnosis.
The images delivered by the system can be used by trained staff as an aid in diagnosis, treatment preparation and radiation therapy planning.
This CT system can be used for low dose lung cancer screening in high risk populations.*
*As defined by professional medical societies. Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information.

Subject Device Indications for Use:

This computed tomography system is intended to generate and process cross-sectional images of patients by computer reconstruction of x-ray transmission data.
The images delivered by the system can be used by trained staff as an aid in diagnosis, treatment and radiation therapy planning as well as for diagnostic and therapeutic interventions.

This CT system can be used for low dose lung cancer screening in high risk populations.*
*As defined by professional medical societies. Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information.

Comparison:
The sentence "The images delivered by the system can be used by a trained physician as an aid in diagnosis" was removed, since the subsequent sentence restates the same, replacing 'trained physician' with 'trained staff'. It can be assumed a trained physician is part of the trained staff.

The word 'preparation' has been removed from the phrase "treatment preparation and radiation therapy planning" since treatment planning better describes how the device is used.

The phrase "as well as for diagnostic and therapeutic interventions" was added to the second sentence. This was done to express use of the device in standard practice. This device can and is commonly used as an aid in invasive procedures.
None of the intended use includes computed tomography as the principal means of guidance in invasive procedures (involving the introduction of a device, such as a needle or a catheter into the body of the patient). The SOMATOM CT Systems are not the principal means of guidance, because the CT Systems does not guide the invasive procedures, the needle orientation and the needle advance and handling is always done under the physicians control.

VII. Comparison of Technological Characteristics with the Predicate Device

The SOMATOM CT Scanner Systems with VB30 software provide the same technological characteristics in terms of materials, energy source, and control mechanisms when compared to the predicate device. The software features of these scanners have been modified or improved in comparison to the predicate devices to support enhanced device functionality compared to the predicate devices. Additionally, the syngo Acquisition Workplace and syngo CT Workplace computers were upgraded due to obsolescence of the predecessor.

The applicable software features are dependent on the SOMATOM CT Scanner Systems technological characteristics and are provided as optional features for updating the installed base. The technological characteristics of the SOMATOM CT Scanner Systems' hardware is a prerequisite for its intended software usage.

The new *syngo* CT VB30 software reuses all unmodified software features of the legacy software *syngo* CT VB20 cleared in K190578. Additionally, no features present in the predicate device are de-scoped.

The intended use and fundamental scientific technology for the SOMATOM Force, SOMATOM Definition Flash, SOMATOM Drive, SOMATOM Definition Edge, SOMATOM Definition AS/AS+, SOMATOM AS Open, SOMATOM Confidence, SOMATOM Edge Plus remain unchanged from the predicate devices.

At a high level, the subject and predicate devices are based on the following same technological elements:

- Scanner Principle- Whole body X-Ray Computed Tomography Scanner
- System Acquisition – Continuously rotating tube detector system
- Iterative Reconstruction – Support of various iterative reconstruction methods
- Workplaces – Support of workplaces that include reconstruction and image evaluation software
- Patient table
- Patient table foot switch for movement

- Tin filtration technology
- Stellar detector technology

The following technological differences exist between the subject and predicate devices:

- Software version SOMARIS/7 syngo CT VB30
- FAST Bolus update for individualized patient scan trigger.
- FAST 3D Camera update to support adolescent patients in addition to adult patients
- FAST applications updates (FAST Spine, FAST Planning)
- Workflow improvements for FAST 4D
- Updated Automatic Patient Instructions
- Recon Jobs limit extended up to 18
- Additional kV setting for Tin Filtration
- Additional default exam scan protocols (e.g. abdomen protocols, Angio-CT, Dual Spiral Dual Energy and ECG gated Flash protocols with tin filtration at high kV)
- syngo Acquisition Workplace and syngo CT Workplace computer upgrades

Any differences in technological characteristics do not raise different questions of safety and effectiveness. Testing and validation is completed. Test results show that the subject devices, the SOMATOM CT Scanner Systems with syngo CT VB30, are comparable to the predicate devices in terms of technological characteristics and safety and effectiveness and therefore are substantially equivalent to the predicate devices.

VIII. Performance data

Non-Clinical Testing

Non-clinical testing, (integration and functional) including phantom tests were conducted for the SOMATOM CT Scanner systems during product development. The modifications described in this Premarket Notification were supported with verification and validation testing.

The general purpose of each test is to verify and validate the functionality of the subject device modifications.

Testing covers related subsystems that contribute to the device modifications. Test levels are defined. For each test level several test activities are performed. The test specification and acceptance criteria are related to the corresponding requirements. Various test activities are performed to specific modifications on different test levels to ensure safe and effective integration in the system. Three test levels are defined:

System Validation test:

- Acceptance test (workflow and user manual test)
- Legal and Regulatory test

System Verification test:

- System Integration Test (functional)
- Functionality verification
- Image Quality (IQ) Evaluation

Tests are conducted for all software components developed in product development and for the complete product itself. Several activities are considered for this process, including creation of test specifications that relate to software/hardware requirements including tests to address risk mitigations that are identified, documented, and traced by hazard keys. The performance data demonstrates continued conformance with special controls for medical devices containing software. The Risk Analysis was completed and risk control implemented to mitigate identified hazards. The testing supports that all software specifications have met the acceptance criteria. Testing for verification and validation support the claims of substantial equivalence.

Bench Testing:

Additional evaluation tests are performed as bench tests to support the device modification on Non-Clinical Performance Testing as listed in the table below.

Feature/ supportive testing	**Bench Testing performed**
FAST Bolus	The bench test evaluates the performance of FAST Bolus. For this purpose, the post bolus delay as calculated by FAST Bolus to an ideal post bolus delay to reach the peak enhancement of a real contrast enhancement curve (determined by measurements with a dynamic scan mode) was calculated. The objectives of the test were to investigate the deviation from the post bolus delay as determined by FAST Bolus to an ideal/ground truth delay measured through three consecutive dynamic scans and respective contrast injections. The results were found in an acceptable margin when compared to averaged dynamic scans, which served as a ground truth for the applied comparison. Supporting Publications for FAST Bolus: Six peer-reviewed scientific studies have been performed before FAST Bolus came to the market. Although these studies have been performed with the prototype(s) of FAST Bolus, there were no functional differences in the FAST Bolus calculation except for in the Korporaal et al. (2015) study described below, which did not consider scan duration. 1. Korporaal JG, Bischoff B, Arnoldi E, Sommer WH, Flohr TG, Schmidt B. Evaluation of A New Bolus Tracking-Based Algorithm for Predicting A Patient-Specific Time of Arterial Peak Enhancement in Computed Tomography Angiography. Investigative Radiology. LWW; 2015;50(8):531–538. This study demonstrated a proof-of-principle and the potential of patient-specific rather than fixed scan delays after bolus tracking. The researchers simulated retrospectively the differences between an optimal personalized scan delay (prototype of FAST Bolus) and a best-case scenario for the conventional bolus tracking technique, using the same group-averaged scan delay for all patients. Main results: Compared with the conventional bolus tracking method, the systematic and random errors of the FAST Bolus prototype were smaller, did not

Feature/ supportive testing	Bench Testing performed
	depend on the IDR, and were predictable over a large range of total iodine doses. The median difference between the true and personalized delay is less than ±1 second for all IDRs and injection durations, and the prototype algorithm was able to predict patient-specific delays within ±2 seconds from the true delay in more than 90% of patients for almost all injection protocols. 2. Hinzpeter R, Eberhard M, Gutjahr R, et al. CT Angiography of the Aorta: Contrast Timing by Using a Fixed versus a Patient-specific Trigger Delay. Radiology. Radiological Society of North America (RSNA); 2019;291(2):531–538https://doi.org/10.1148/radiol.2019182223 This study included prospective CT angiography scans of the aorta. A total of 108 patients received a patient-specific trigger delay (FAST Bolus prototype) and another 108 patients the regular fixed trigger delay of 4 seconds (reference group). Main results: There was higher overall and more uniform attenuation in the individualized cohort compared to the fixed cohort. No difference between the cohorts for image noise was found, but a higher contrast-to-noise ratio (CNR) and higher subjective image quality in the individualized cohort compared to the fixed cohort. 3. Gutjahr R, Fletcher JG, Lee YS, et al. Individualized Delay for Abdominal Computed Tomography Angiography Bolus-Tracking Based on Sequential Monitoring: Increased Aortic Contrast Permits Decreased Injection Rate and Lower Iodine Dose. Journal of computer assisted tomography. LWW; 2019;43(4):612–618 The group studied whether the individualized trigger delay from the FAST Bolus prototype would facilitate reductions in injection rate and iodine dose in abdominal CTA. The study population consisted of three groups: 20 patients with routine injection rate and iodine dose; 20 patients with an injection rate lowered by 1 mL/s; and 40 patients with an injection rate lowered by 1 mL/s and an iodine dose reduction of 29%. Main results: The median trigger delay was significantly longer than with conventional bolus tracking (mean increase 13.3 seconds), with image quality being the same or better. Intra-arterial CT numbers were at least 200 Hounsfield units for all CTAs in all three sub-groups with the FAST Bolus prototype. In the internal control group and the size-matched control patients with the standard fixed scan delay, 12% and 14% of patients did not reach the 200 HU in the abdominal CTA respectively. So the FAST Bolus prototype was able to adjust the scan timing to the altered scan protocols to reach diagnostic image quality in

Feature/ supportive testing	Bench Testing performed
	abdominal CTA examinations despite slower injection rate and reduced iodine dose. 4. Yu J, Lin S, Lu H, et al. Optimize scan timing in abdominal multiphase CT: Bolus Tracking with an Individualized Post-trigger Delay. European Journal of Radiology. Elsevier; 2021;110139 The group conducted a head-to-head comparison on the image quality and diagnostic confidence between an individualized post-trigger delay with the FAST Bolus prototype and a conventional fixed post-trigger delay in abdominal multiphase CT. Abdominal multiphase CT was performed in 104 patients with either the FAST Bolus prototype (group A) or a fixed post-trigger delay of 11 seconds (group B). Main results: In the arterial phase, the images of group A with the individualized post-trigger delay provided higher attenuation for all organs (aorta, liver, pancreas, and portal vein). Furthermore, the contrast-to-noise ratio (CNR) of liver, pancreas and portal vein were significantly higher in the group with the individualized scan timing compared to the fixed scan delay. The overall subjective image quality and diagnostic confidence between the two groups were similar. 5. Yuan D, Wang Y, Lin S, et al. Patient-specific post-trigger delay in coronary CT angiography: A prospective study comparing with fixed delay. European Journal of Radiology. Elsevier; 2023;163:110813 From the same hospital as the previous paper, Yuan et al validated the peak enhancement timing of a patient-specific post-trigger delay (FAST Bolus prototype) in coronary CT angiography (CCTA) and compare its image quality against a fixed scan delay. In this prospective study, 204 consecutive participants were randomly divided into two groups and underwent CCTA with either a fixed 5-second scan delay (Group A, 102 patients) or a patient-specific scan delay with the FAST Bolus prototype (Group B, 102 patients). Test bolus was also performed in Group B to determine the reference peak enhancement timing. Main results: The scan timing from the FAST Bolus prototype demonstrated strong correlation and consistency with the reference peak timing from the test bolus scans in Group B. Both readers rated better subjective image quality for Group B with the individualized scan timing. Also, the mean vessel enhancement was significantly higher in Group B in all coronary vessels. After adjusting for the patient variation, the FAST Bolus prototype was associated with an average of 33.5 HU higher enhancement compared to the fixed PTD. 6. Schwartz FR, Ramirez-Giraldo JC, Gutjahr R, Boll D, Koweek LM. Poster: Real-Time Patient Specific Scan Initiation for Pulmonary Embolism CTA: Impact on

Feature/ supportive testing	Bench Testing performed
	Image Quality. Society of Computed Body Tomography and Magnetic Resonance Annual Meeting. 2018 Purpose: Real time modulation of scan initiation based on patient specific hemodynamics may allow for optimal timing of contrast enhancement in the pulmonary arteries when using fluoroscopic triggering, especially in segmental and sub-segmental vessels, and reduce the number of non-diagnostic scans. Conclusion: The diagnostic delay calculated by the Real Time Patient Specific Modulation (RTPSM) software achieved higher contrast opacification and image quality while reducing the number of non-diagnostic PA segments by 7.4% in PE chest CTA compared to a fixed diagnostic delay. A patient specific diagnostic delay determination can target the contrast bolus to the pulmonary arterial system more efficiently and reduce the amount of contrast in the central veins.
FAST 3D Camera	With SOMARIS/7 syngo CT VB30 software version the feature FAST 3D Camera is extended to support both adult and adolescent patients. The optimizations affect the FAST Isocentering, FAST Range, and FAST Direction sub-features. The objective of the test is to demonstrate that the FAST 3D Camera feature of the subject devices SOMATOM CT Scanner Systems with SOMARIS/7 *syngo* CT VB30, which was extended to support adolescent patients, achieves comparable or more accurate results than the predicate devices with software version *syngo* CT VB20 for adult patients, while supporting adolescent patients of height 120 cm or taller with comparable accuracy as adult patients. FAST Isocentering: The lateral isocenter accuracy of the subject device is comparable to the predicate device for adult patients. Moreover, the subject device achieves similar accuracy also for adolescent patients. FAST Range: The robustness of the groin landmark is improved in the subject device, while the other landmarks are detected with comparable accuracy. For adolescents, the accuracy of the landmark detection of the subject device is of similar accuracy as for adults. FAST Direction: The subject and predicate device have comparable accuracy of the pose detection.
FAST Planning	The purpose of the test is to provide a clear reporting on the applied algorithm, its product development, validation, and verification on patient data, which enable the claims. Objective of the test was to assess the fraction (percentage) of ranges calculated by the FAST Planning algorithm that are correct and can be applied without change.

Feature/ supportive testing	Bench Testing performed
	Additionally, calculation time was measured to check whether it meets interactive requirements. The test results showed that the editing actions for the scanner technician can be reduced to a minimum and that the calculation time is fast enough for interactive speed during scanning. For more than 90% of the ranges no editing action was necessary to cover standard ranges. For more than 95%, the speed of the algorithm was sufficient.
Tin Filtration	The bench test contains two aspects. First, the successful implementation of these two new voltage combinations is verified by validation measurements and a description of the spectral properties is given. Second, tests to support claims regarding improved contrast-to-noise ratio (CNR) in spectral results, i.e., monoenergetic images, are provided. The results show the successful implementation of the two new voltage combinations 80/Sn140 kV and 100/Sn140 kV with Sn filter of the Dual Spiral Dual Energy mode on the P46 system is verified via phantom scans and an evaluation of image quality criteria. This includes different kinds of images, such as low-kV and high-kV images, mixed images, virtual monoenergetic images and Rho/Z images. All applied tests concerning image quality passed. The different spectral properties of the different voltage combinations with and without Sn filter are evident from the presented results. The Sn filter improves spectral separation considerably. The results support claims related to improved CNR in DE-derived virtual monoenergetic images due to tin filtration. The document serves as collection to document bench tests that have been performed for the evaluation of tin filter technology. The reported bench tests have been performed on a variety of SOMATOM CT devices. Since the physical principle remains the same, similar results can be expected for all Siemens Healthineers CT scanners equipped with tin filter technology.

Cybersecurity

Siemens 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. Cybersecurity information in accordance with guidance document “Content of Premarket Submissions for Management of Cybersecurity Medical Devices issues on October 2, 2014” is included within this submission.

IX. Conclusions

The predicate devices were cleared based on the results of non-clinical testing including verification and validation, phantom tests, and supportive literature. 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 SOMATOM CT Scanner Systems should perform as intended in the specified use conditions. The data included in this submission demonstrates that the SOMATOM CT Scanner Systems perform comparably to the predicate devices currently marketed for the same intended use. Since all predicate devices were tested using the same methods, Siemens believes that the data generated from the SOMATOM CT Scanner Systems testing supports a finding of substantial equivalence.