



Subtle Medical, Inc.
Adam Heroux
Quality Engineering and Regulatory Affairs Manager
4190 Grove St
Denver, Colorado 80211

Re: K254120
Trade/Device Name: SubtleHD-CT (1.x)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: April 11, 2026
Received: April 13, 2026

Dear Adam Heroux:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,



Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K254120

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Please provide the device trade name(s).

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SubtleHD-CT (1.x)

Please provide your Indications for Use below.

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SubtleHD-CT is an AI/ML software intended for the processing and enhancement of CT images regardless of the manufacturer or model of CT scanner.

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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SubtleHD-CT 510(k) Summary

Table 1. Contact Details and Device Name

Date Summary Prepared:	10 April 2026
<u>Contact Details:</u>	
Company Name:	Subtle Medical, Inc.
Company Address:	883 Santa Cruz Ave, Suite 205 Menlo Park, CA 94025 United States
Applicant Name:	Mr Ajit Shankaranarayanan
Application Telephone:	650-448-4285
Applicant Email:	Ajit@subtlemedical.com
Correspondent Name:	Highland Biomedical
Correspondent Address:	4190 Grove St Denver, CO 80211
Correspondent Contact:	Mr. Adam Heroux
Correspondent Contact Telephone:	617-823-0515
Correspondent Contact Email:	regulatory@subtlemedical.com
<u>Device Name:</u>	
Device Trade Name	SubtleHD-CT (1.x)
Common Name:	Medical image management and processing system
Classification Name:	System, Image Processing, Radiological
Regulation Number:	892.2050
Product Code:	QIH
Device Class:	Class II
Legally Marketed Predicate Devices:	Primary Predicate #: K212074 Primary Predicate Name: ClariCT.AI Primary Predicate Legal Manufacturer: Claripi

Device Description Summary

SubtleHD-CT is an image processing Software as a Medical Device (SaMD) consisting of a deep learning artificial intelligence/machine learning (AI/ML) to enhance medical images acquired by computed tomography (CT) scanners. It is post-processing software that does not directly interact with the scanner. Once a CT scan is acquired, a technologist sends the study from the scanner to a compatible medical device data system (MDDS) via the DICOM protocol. The compatible MDDS, then, makes the images available to SubtleHD-CT for processing. The study is enhanced by SubtleHD-CT and sent back to the picture archiving and communication system (PACS) or other DICOM node by the compatible MDDS for clinical review. Please note that interpretation of SubtleHD-CT's output should be adjunctive to the original reconstructed image. Because the software runs in the background, it has no user interface. Configuration is specified as configuration files and OS environment variables.

The SubtleHD-CT software implements an image enhancement algorithm using a convolutional neural network. Input images are enhanced by running through the CNN that consists of cascaded layers to perform numerical operations, including convolutional filtering, linear combination, and nonlinearity operations.

Intended Use / Indications for Use

SubtleHD-CT is an AI/ML software intended for the processing and enhancement of CT images regardless of the manufacturer or model of CT scanner.

Intended Use / Indications for Use Comparison

SubtleHD-CT and its predicate are both intended to enhance CT images regardless of the manufacturer or model of CT scanner.

Technological Comparison

SubtleHD-CT and its predicate are used for image enhancement. They operate on DICOM files, enhance the images, and send the enhanced images to any desired destination. The receipt of original DICOM image files and delivery of enhanced images as DICOM files depends on other software systems. Both the subject and predicate device use pre-trained deep learning models. The software performs image enhancement. The following table provides a detailed description of the technological characteristics of the subject and predicate device.

SubtleHD-CT v1.x is classified as Class II with product code QIH through the FDA using ClariCT.AI as predicate.

Table 2. Comparison of Technological Characteristics

Comparison	SubtleHD-CT (Subject Device)	ClariCT.AI (K212074)	Noted Differences
Product Code	QIH	LLZ	Substantially Equivalent
Modalities	CT	Same	Same

Comparison	SubtleHD-CT (Subject Device)	ClariCT.AI (K212074)	Noted Differences
Intended Use / Indications for Use	SubtleHD-CT is an AI/ML software intended for the processing and enhancement of CT images regardless of the manufacturer or model of CT scanner.	ClariCT.AI is a software device intended for networking, communication, processing and enhancement of CT images in DICOM format regardless of the manufacturer of the CT scanner or model.	Substantially Equivalent
Product Description	SubtleHD-CT is an AI/ML image processing Software as a Medical Device (SaMD) consisting of a deep learning artificial intelligence/machine learning (AI/ML) to enhance medical images acquired by computer tomography (CT) scanners. SubtleHD-CT can enhance CT images of the abdomen, c-spine, cardiac, chest, chest-abdomen-pelvis (CAP), head, head & neck, l-spine, lower-extremity, MSK, t-spine, and upper-extremity acquired on a wide range of CT doses.	ClariCT.AI software is intended for denoise processing and enhancement of CT DICOM images when higher image quality and/or lower dose acquisitions are desired. ClariCT.AI software can be used to reduce noises in CT images of the head, chest, heart, and abdomen, in particular in CT images with a lower radiation dose. ClariCT.AI may also improve the image quality of low-dose nondiagnostic Filtered Back Projection images as well as Iterative Reconstruction images.	Substantially Equivalent
Workflow	The software operates on DICOM files, enhances the images, and sends the enhanced images to any desired destination with an AE Title (e.g., PACS, CT device, workstation, and more). Enhanced images coexist with the original images.	ClariCT.AI can seamlessly integrate with PACS and the existing user site infrastructure using features provided by syngo.via. The recommended setting is to automate the whole workflow from taking an exam using a CT scanner to viewing the denoised image in the radiologist's reading environment.	Substantially Equivalent

Comparison	SubtleHD-CT (Subject Device)	ClariCT.AI (K212074)	Noted Differences
Physical Characteristics	Software package Operates on a virtual machine	Window or Linux Operating System. PC Hardware supported graphics card or equivalent. Docker images in a virtual machine.	Substantially Equivalent
Intended User	Radiologists	Same	Same
Intended Location	Medical facility (hospitals, clinics, imaging center, etc.)	Same	Same
Operating System / Computer	Linux Compatible; PC or Mac	Can be integrated into the AI Marketplace system that distributes Docker images in a virtual machine running in a Linux environment.	Substantially Equivalent
Rx or OTC	Rx	Same	Same
User Interface	Runs in the background (no user interact)	GUI mode and Background mode. MixView to view original and denoised images side-by-side for easy image quality comparison.	Both have background modes, ClariCT.AI has an optional user interface. Substantially Equivalent
DICOM Standard Compliance	The software processes DICOM-compliant image data.	Same	Same
Image Enhancement Algorithm Description	Image enhancement is performed with the use of pre-trained deep learning models.	Noise reduction is performed with the use of pre-trained deep learning models.	Substantially Equivalent
Model Architecture	One model is used for image enhancement of CT.	Pre-trained deep learning models.	Substantially Equivalent

Non-Clinical and/or Clinical Tests Summary & Conclusions

Subtle Medical conducted the following performance testing:

- Software Verification and Validation testing (unit, integration, and system testing) to demonstrate that software requirements are implemented. These tests **PASSED**.
- Performance Validation testing utilizing ACR Phantom, Digital CatPhan Phantom, and Mercury 4.0 Phantom to demonstrate the software enhanced image quality. These tests **PASSED**.
- A Reader Study utilizing retrospective clinical data to demonstrate the software enhanced image quality in CT images. These tests **PASSED**.

Performance Phantom Characteristics:

The performance validation utilized industry standard phantoms:

- CT ACR phantom: used by the proposed predicate device.
- Digital CatPhan Phantom 600: from the FDA's Division of Imaging, Diagnostics, and Software Reliability (DIDSR).
- Mercury 4.0 Phantom

Reader Study Dataset Characteristics:

To represent the patient population and use of CT in the field, the SubtleHD-CT performance and reader study validation test dataset consists of:

- Split between all anatomies (abdomen, c-spine, cardiac, chest, chest-abdomen-pelvis (CAP), head, head & neck, l-spine, lower-extremity, MSK, t-spine, upper-extremity).
- Canon, GE Medical Systems, Hitachi, Philips, and Siemens scanner vendors.
- Pediatric (adolescent, children) and adult subjects (ranging from 3 to 90 years old).
- Even distribution of subject sex.
- Contrasted and non-contrasted images.
- Various reconstruction methods (FBP, IR, DLR).
- Various slice thicknesses: between 0.5 mm and 15 mm
- Various FOV: between 113mm and 1246 mm.
- Axial, coronal, sagittal, and oblique orientations.
- Various imaging acquisition parameters (XRay Tube Current, Exposure, kVP, Pixel Size).
- 64 unique kernels representing various reconstructions (soft, standard, and sharp) performed for the wide range of clinical protocols in different scanner manufacturers.

Summary of CT DIvol dose levels represented in the clinical cases used in the reader study

<i>CT Protocol</i>	Minimum Dose (mGy)	Average Dose (mGy)	Maximum Dose (mGy)
Abdomen	2.75	12.94	45.50
C-Spine	2.10	11.29	28.68
Cardiac	2.10	15.99	55.28
Chest	0.90	5.47	15.07

Chest-Abd-Pelvis	2.86	11.25	27.84
Head	13.37	38.47	68.50
Head-Neck	1.35	10.70	39.06
L-Spine	8.87	19.78	32.78
Lower-Extremity	3.73	10.05	18.88
MSK	15.50	15.50	15.50
T-Spine	4.11	13.75	29.72
Upper-Extremity	0.93	10.75	21.03
Min/Avg/Max	0.90	15.38	68.50

Various clinical conditions are present in the performance dataset, as per reports accompanying the images from the sources, including: chronic sinusitis, trauma, stroke, head injury, osteosarcoma, dissection, pain, fracture, mass/tumor, aneurysm, calcium scoring, coronary CTA, etc. Some clinical conditions were not reported with the data. This selection criteria represents a well characterized clinically-relevant reference dataset.

To show the performance of the device was not hindered by site variability, in the validation dataset, data was selected from sources not included in the training dataset. The majority of performance data comes from sources in the United States. Independence between the training and test datasets was ensured by using non-overlapping datasets, with no shared subjects, studies, or images between training and testing.

Performance Validation:

The quantitative performance validation for SubtleHD-CT was conducted exclusively using phantom data. Specifically, testing utilized the CT ACR 464 phantom, the Digital CatPhan 600 phantom, and the Mercury 4.0 phantom. As part of the quantitative evaluation: CT Number Accuracy, Image Noise (Magnitude), Image Non-Uniformity (NU), Spatial Resolution (Task Transfer Function - TTF), Noise Texture (Noise Power Spectrum - NPS), Detectability Index (d') were characterized when compared to traditional FBP reconstructions. Where applicable, testing relied on simulated targets rather than clinical anomalies to estimate task-based clinical utility, such as how well a signal or lesion can be detected given the image resolution and noise properties.

SubtleHD-CT's quantitative performance was validated on these phantoms for CT images reconstructed via standard Filtered Back Projection (FBP), acquired using standard-dose or higher-dose protocols.

The software is engineered to complement the characteristics of FBP-based imaging; use with Iterative Reconstruction (IR) or Deep Learning (DL)-based reconstructions may result in unknown performance. Please refer to Table 4 for more details.

SubtleHD-CT has been validated for use on primary reconstructed images. Performance has not been specifically characterized on images that have undergone advanced third-party

post-processing or specialized non-standard filtering. It is recommended to apply SubtleHD-CT enhancement to the direct output of the CT scanner's primary reconstructed images.

For the assessment of task-based image quality on the ACR phantom, Digital CatPhan and Mercury 4.0 phantoms, simulated lesions of varying diameters and contrasts were used to mimic low-contrast detectability across different tasks. **Table 3** summarizes the target characteristics of the tasks performed.

Table 3: Simulated Target Characteristics for ACR 464, Digital CatPhan 600 and Mercury 4.0 Phantoms

Phantom	Target type	Target sizes	Target Contrasts / Materials
ACR 464	Simulated circular lesions in varying backgrounds	3mm, 4mm, 5mm, 6mm, 7mm	Materials: Air, Polystyrene, Acrylic, Bone. Each material was evaluated at 5 varying contrasts.
Digital CatPhan 600	Simulated circular lesions	3mm, 5mm, 7mm, 10mm	14 HU, 7 HU, 5 HU, 3 HU (respectively)
Mercury 4.0	Simulated circular lesion in varying backgrounds	1mm	Air, Water, Bone, Polystyrene, Iodine

Phantom Testing Details: To characterize the performance of SubtleHD-CT, phantoms were tested across multiple vendor scanners (GE, Siemens, and Canon) using a wide variety of scanning parameters. Across the full dataset, testing encompassed a wide operational range including slice thicknesses from 0.28 to 5 mm, reconstruction fields of view (FOV) from 144 to 500 mm, CTDIvol of 0.2 to 20.6 mGy and pixel size from 0.28 to 0.98 mm. Furthermore, the Mercury 4.0 phantom consists of 5 cylindrical modules composed of Polyethylene, varying in diameter from 16, 21, 26, 31, and 36 cm to represent varying patient sizes. **Table 4** summarizes the key acquisition parameters.

Table 4: Evaluated Acquisition Parameters for ACR 464, Digital CatPhan 600 and Mercury 4.0 Phantom scans

Phantom	Pixel size (mm)	FOV (mm)	Matrix Size	Slice Thickness (mm)	FBP Kernel	CTDIvol (mGy)	kVp (kV)	X-ray Tube Current (mA)	Vendor
ACR 464	0.488	250	512 x 512	1	B30f	3.38	120	60	Siemens
	0.488	250	512 x 512	1	D45f	3.38	120	60	Siemens
	0.488	250	512 x 512	3	B30f	3.38	120	60	Siemens
	0.488	250	512 x 512	3	D45f	3.38	120	60	Siemens
Digital CatPhan 600 (13 cm)	0.281	144	512 x 512	0.28	fbp D45	/	120	170	Siemens(simula- te d)
	0.281	144	512 x 512	0.28	fbp D45	/	120	170	Siemens(simula- te d)
Mercury 4.0	0.586	300	512 x 512	5	STAND ARD	/	100	205	GE
	0.586	300	512 x 512	5	STAND ARD	/	120	130	GE
	0.586	300	512 x 512	5	STAND ARD	/	140	90	GE
	0.586	300	512 x 512	5	STAND ARD	/	80	380	GE
	0.977	500	512 x 512	4	Br38s	6	70	494	Siemens
	0.977	500	512 x 512	4	Br38s	12.65	80	646	Siemens
	0.977	500	512 x 512	4	Br38s	19.72	100	475	Siemens
	0.977	500	512 x 512	4	Br38s	20.25	120	285	Siemens
	0.977	500	512 x 512	4	Br38s	20.6	140	190	Siemens
	0.702	360	512 x 512	1	Body+ BHC	0.4	80	209	Canon
	0.977	500	512 x 512	1	Body	0.2	120	40	Canon

The following are the endpoints, acceptance criteria, results, and conclusions from the SubtleHD-CT performance validation study:

Table 5. Performance Validation Summary

Endpoint	Acceptance Criteria	Results / Conclusions
Detectability Index (d') Primary Endpoint	The detectability index (d') value of the SubtleHD-CT enhanced outputs must be equal to or greater than the corresponding value obtained from the unenhanced filtered back projection (FBP) inputs across all evaluated clinical tasks.	PASS: For SubtleHD-CT as compared to the unenhanced FBP, across all phantoms and all evaluated clinical tasks the SubtleHD-CT detectability index (d') was greater than the unenhanced FBP.
Image Noise (Magnitude) Primary Endpoint	The noise magnitude of the SubtleHD-CT enhanced outputs shall be statistically significantly lower, p-value < 0.05 level with a Student's t-test, than that of the unenhanced filtered back projection (FBP) inputs.	PASS: Across all phantoms the image noise magnitude was statistically significantly lower, p-value < 0.05 level with a Student's t-test, than that of the unenhanced filtered back projection (FBP) inputs.
Noise Texture (Noise Power Spectrum - NPS) Secondary Endpoint	The NPS average frequency (f_{av}) and peak frequency (f_{peak}) of the SubtleHD-CT outputs shall be < 0.5 cycles/mm relative to unenhanced filtered back projection (FBP) inputs.	PASS: For SubtleHD-CT as compared to the unenhanced FBP, across all phantoms, scanner parameters, and diameters the NPS average frequency (f_{av}) and peak frequency (f_{peak}) for the SubtleHD-CT outputs was < 0.5 cycles/mm relative to the unenhanced filtered back projection (FBP) inputs.
CT Number Accuracy Secondary Endpoint	The CT number accuracy shall remain within ± 5 hounsfield units (HU) of the unenhanced filtered back projection (FBP) inputs.	PASS: For SubtleHD-CT as compared to the unenhanced FBP, the CT number accuracy was within ± 5 hounsfield units (HU) of the unenhanced filtered back projection (FBP) inputs.
Image Non-Uniformity (NU) Secondary Endpoint	The difference between the mean CT value of each peripheral ROI and the center ROI shall be < 5 hounsfield units (HU).	PASS: The mean CT value of each peripheral ROI and the center ROI for both the Digital CatPhan Phantom and ACR Phantom remains within 5 hounsfield units.

Endpoint	Acceptance Criteria	Results / Conclusions
Spatial Resolution (Target Transfer Function - TTF) Secondary Endpoint	The TTF curve at 50% (f_{50}) and 10% (f_{10}) of the TTF shall be < 1.2 lp/cm of the unenhanced filtered back project (FBP) inputs.	PASS: Across all ROIs for all the phantoms, the range of the TTF curve at 50% (f_{50}) and 10% (f_{10}) of the TTF was < 1.2 lp/cm of the unenhanced filtered back project (FBP) inputs.

Reader Study:

This study utilized 270 cases of retrospectively acquired human data obtained as part of research studies or clinical exams from various institutions. The datasets were presented side-by-side with original and SubtleHD-CT enhanced images.

Board-certified radiologists evaluated SubtleHD-CT enhanced images for diagnostic utility using a 5-point Likert scale and artifact presence using a 3-point Likert scale.

The following are the endpoints, acceptance criteria, results, and conclusions from the SubtleHD-CT Reader Study:

Table 6. Reader Study Summary

Endpoint	Acceptance Criteria	Results / Conclusions
Diagnostic Utility Endpoint	The diagnostic utility of the SubtleHD-CT images is the same or better than the original images.	PASS: The average scores across all readers of the SubtleHD-CT enhanced images are an average of 3 or better (enhanced images are the same or better than original).
Artifact Presence Endpoint	SubtleHD-CT does not introduce artifacts that could impact diagnosis in any image.	PASS: SubtleHD-CT enhanced images have an average of 2 or better (SubtleHD-CT does not introduce artifacts that impact diagnosis in any image).

Conclusion:

These results demonstrate that SubtleHD-CT is substantially equivalent to the predicate devices.