DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 30, 2016

Siemens Medical Solutions, Inc.
% Mr. John Urtz
Regulatory Affairs Specialist
40 Liberty Boulevard, Mail Code 65-1A
MALVERN PA 19355

Re: K153360
Trade/Device Name: ADMIRE
Regulation Number: 21 CFR 892.1650
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: June 21, 2016
Received: June 21, 2016

Dear Mr. Urtz:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K153360

Device Name
ADMIRE

Indications for Use *(Describe)*

ADMIRE is a CT reconstruction software. The end user can choose to apply either ADMIRE or the weighted filter back-projection (WFBP) to the acquired raw data. Depending on the clinical task, patient size, anatomical location, and clinical practice, the use of ADMIRE can help to reduce radiation dose while maintaining pixel noise, low contrast detectability and high contrast resolution.

Phantom measurements showed that high contrast resolution is equivalent or improved and pixel noise is equivalent between full dose WFBP images and reduced dose ADMIRE images. Additionally, ADMIRE can reduce spiral artifacts by using iterations going back and forth between image space and raw data space.

Images reconstructed with ADMIRE are not intended to be evaluated with syngo Osteo CT or syngo Calcium Scoring.

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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SIEMENS

510(k) Summary
For
ADMIRE

Submitted by:
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Mail Code 65-1A
Malvern, PA 19355

June 21, 2016

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

1. General Information

Importer / Distributor
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Mail Code 65-1A
Malvern, PA 19355
Establishment Registration Number: 2240869

Manufacturing Site
Siemens Healthcare GmbH
Siemensstrasse 1
Forchheim Bayern, Germany 91301
Establishment Registration Number: 3004977335

2. Contact Person:

Mr. John Urtz
Regulatory Affairs Specialist
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Mail Code 65-1A
Malvern, PA 19355
Phone:(610) 448-6002 Fax: (610) 640-4481

3. Device Name and Classification

Product/Trade Name:	ADMIRE
Classification Name:	Computed Tomography X- ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	90 JAK

4. Device Description

ADMIRE is an iterative reconstruction option designed to be used on Siemens currently marketed and future CT devices. Its use has been previously cleared by FDA (K133646, clearance date June 20, 2014). No modifications were made to the algorithm or to the implementation of the feature. The changes proposed within this 510(k) only pertain to an extension of the claims associated with the feature as follows:

1) Compared to images reconstructed with WFBP, ADMIRE may simultaneously enable*
   - 80 to 85% dose reduction at the same image quality and
   - 73 to 77% image noise reduction at the reduced dose and
   - up to 42% improved high-contrast spatial resolution improvement at reduced dose and reduced image noise.

2) Alternatively, ADMIRE may enable*
   - up to 150% improved low contrast detectability (factor 2.5) at the same dose or
   - up to 90% image noise reduction at constant dose or
   - up to 87% improved high-contrast spatial resolution improvement at 85% reduced dose and constant image noise or
   - up to 38% improved high-contrast resolution at 90% reduced image noise and constant dose.

Furthermore, the following claims have previously been cleared by FDA as part of K133646 (clearance date June 20, 2014) and will be maintained with this clearance:

3) Additionally, ADMIRE
   - compared to SAFIRE potentially features a more "FBP-like" noise texture in terms of the number of "outliers" in the noise texture, especially for higher strength settings of the algorithm and
   - can reduce spiral artifacts by using iterations going back and forth between image space and raw data space and
   - has the potential to result in a higher noise reduction compared to SAFIRE when reconstructing thick slices.

* Image quality as defined by low contrast detectability using a model observer method for evaluation. Equivalent low contrast detectability can be achieved with 80% to 85% less dose using ADMIRE at highest strength level for thin (0.6 mm) reconstruction slices in measured and simulated body and head phantoms for low contrast objects with different contrasts. See ADMIRE data sheet for further information.

In clinical practice, the use of ADMIRE may reduce CT patient dose depending on the clinical task, patient size, anatomical location, and clinical practice. A consultation with a radiologist and a physicist should be made to determine the appropriate dose to obtain diagnostic image quality for the particular clinical task.

5. Intended Use

ADMIRE is a CT reconstruction software. The end user can choose to apply either ADMIRE or the weighted filter back-projection (WFBP) to the acquired raw data. Depending on the clinical task, patient size, anatomical location, and clinical practice, the use of ADMIRE can help to reduce radiation dose while maintaining pixel noise, low contrast detectability and high contrast resolution.

Phantom measurements showed that high contrast resolution is equivalent or improved and pixel noise is equivalent between full dose WFBP images and reduced dose ADMIRE images. Additionally, ADMIRE can reduce spiral artifacts by using iterations going back and forth between image space and raw data space.

Images reconstructed with ADMIRE are not intended to be evaluated with *syngo* Osteo CT or *syngo* Calcium Scoring.

6. Substantial Equivalence:

Siemens ADMIRE SW package with new claims is substantially equivalent to the following medical device in commercial distribution

Predicate Device Name	*FDA Clearance Number*	*FDA Clearance Date*
ADMIRE	*K133646*	*06/20/2014*

7. Summary of Technological Characteristics of the Principal Device as Compared with the Predicate Device

ADMIRE is an iterative reconstruction option that may be utilized with all CT scanners offered by Siemens and its use has been previously cleared by FDA (K133646, clearance date June 20, 2014).
No modifications were made to the algorithm or to the implementation of the feature. The changes proposed within this 510(k) only pertain to an extension of the claims associated with the feature.

The intended use and fundamental scientific technology are identical to the predicate devices; therefore Siemens believes that they are substantially equivalent to the predicate devices.

8. Verification and Validation

Non clinical tests were conducted for ADMIRE software package during product development. The dose savings potential of ADMIRE was determined based on evaluations of low-contrast detectability (LCD) in reconstructed images of the PhantomLabs® CCT189 and CCT191 phantoms using model observer studies. Using the same reconstructed images, image noise was determined by computing the standard deviation across images at all pixel locations. Both computer-simulated as well as measured CT data was utilized for these tasks to facilitate the generation of a large number of CT images at different dose levels for a thorough evaluation. The assessment of high-contrast spatial resolution was based on measured CT data of a Teflon edge phantom as defined by the ImPACT CT evaluation group.

No new risks were identified for ADMIRE with quantitative dose reduction claims. The testing results support that all software specifications have met the acceptance criteria. Testing for verification and validation of the device was found acceptable to support the claims of substantial equivalence and the claims presented in the Device Description above.

9. General Safety and Effectiveness Concerns

Instructions for use are included within the device labeling, and the information provided will enable the user to operate the device in a safe and effective manner. No instructions for use have changed with respect to the predicate device.

Furthermore, the operators are health care professionals familiar with and responsible for the X-ray examinations to be performed. To minimize electrical, mechanical and radiation hazards, Siemens adheres to recognized and established industry practice, and all equipment is subject to final performance testing.

10. Conclusion as to Substantial Equivalence

Siemens Computed Tomography X-ray systems, configured with SOMARIS software including ADMIRE are intended for the same indications for use as the predicate device. Further, the additional claims do not introduce new or changed technological characteristics and the data included supports these claims. Thus, a determination of substantial equivalence is warranted.