GE Healthcare
510(k) Premarket Notification Submission for ASiR-V

510(k) Summary of Safety and Effectiveness

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirement of 21 CFR Part 807.87(h).

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	November 26, 2013
Submitter:	GE Healthcare GE Healthcare (GE Medical Systems, LLC) 3000 N. Grandview Blvd., W-1140 Waukesha, WI 53188
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Product Identification:	ASiR-V
Device Trade Name:	GE ASiR-V Reconstruction Option
Common/Usual Name:	Computed Tomography X-ray System
Classification Names:	Computed Tomography X-ray System per 21CFR 892.1750
Product Code:	90-JAK
Predicate Device	K103489 - Veo Reconstruct option K093581 – Discovery CT590/Optima CT580 (includes a robust analysis of ASiR)
Manufacturer: /Design Location:	GE Healthcare Japan Corporation 7-127 Asahigaoka, 4-chome, Hino-shi Tokyo, 191-8503, Japan

Manufacturing location (s):	GE Healthcare Japan Corporation 7-127 Asahigaoka, 4-chome, Hino-shi Tokyo, 191-8503, Japan And GE Medical Systems, LLC 3000 N. Grandview Blvd. Waukesha, WI 53188, USA And GE Hangwei Medical Systems, Co, Ltd No.1, YongChang Street, Beijing Economic & Technical Development Area, Beijing PR, Beijing, 100176, China
Distributor:	GE Medical Systems, LLC 3000 N. Grandview Blvd. Waukesha, WI 53188, USA

Marketed Devices:

The GE ASiR-V Reconstruction Option when combined with the GE CT system is of comparable type and substantially equivalent to the Veo Reconstruct option (K103489) and Discovery CT590/Optima CT580 (K093581) including a robust analysis of ASiR which are legally marketed devices currently in commercial distribution.

ASiR-V is the next generation of ASIR and leverages some of the design features of Veo. ASiR was originally cleared in K081105 and K082761, however FDA conducted a more rigorous review of ASiR as part of K093581. ASiR has since been cleared with numerous other GE CT system 510k's. Veo was cleared in K103489.

Device Description:

The GE ASiR-V Reconstruction Option is an alternate CT image reconstruction option for GE CT Systems to Filtered Back Projection, the advanced GE iterative reconstruction software Veo Reconstruction Option (K103489) and the ASiR reconstruction option.

This reconstruction technique is the advanced GE iterative reconstruction method intended to be used when higher image quality and/or lower dose acquisitions are desired for all routine cases to improve image performance such as Low Contrast Detectability, Image Noise, Spatial Resolution, artifact reduction, etc. Image quality improvements and dose reduction depend on the clinical task, patient size, anatomical location, and clinical practice.

The GE ASiR-V Reconstruction Option when used with the CT System performs as well as or better than Filtered Back Projection and uses operating principles derived from ASIR and Veo.

ASiR-V has been designed for use with GE CT scanners and has been bench tested and clinically evaluated on three product platforms in order to demonstrate its robustness and operability.

With the ASiR-V Reconstruction Option, the user has the option to use ASiR-V and/or reconstruct images with the other reconstruction methods already available on the GE CT systems. ASiR-V is available for retrospective reconstruction.

Intended Use:
The ASiR-V Reconstruction Option is intended for head and whole body CT scans when higher image quality and/or lower dose acquisitions are desired.

Indications for Use:
The ASiR-V Reconstruction Option is intended to produce cross-sectional images of the head and body by computer reconstruction of X-ray transmission data taken at different angles and planes, including Axial, Helical (Volumetric), and Cardiac acquisitions for all ages.

When used, it allows for an alternate reconstruction method designed to reduce image noise and streak artifact, increase resolution and improve low contrast detectability in images produced using raw Computed Tomography data from the GE CT scanner. The ASiR-V Reconstruction Option can be used to reduce noise in images and also to reduce the dose required for diagnostic CT imaging, including scans of the head, chest, heart, abdomen and pelvis. The ASiR-V Reconstruction Option may also improve the image quality of low dose non-diagnostic Filtered Back Projection images such that they become diagnostic.

ASiR-V reconstruction option is for use with the GE CT Scanners.

Potential Adverse Effects on Health:
Potential hazards are identified in a risk management including hazard analysis and controlled by:

● System verification and validation to ensure performance to specifications, Federal Regulations, and user requirements.
● Adherence to software development lifecycle procedures (SDLC)
● Instruction for Use provided for the safe an effective use by users.

The device is designed and manufactured under the Quality System Regulations of 21 CFR 820.

Determination of Substantial Equivalence:
The GE ASiR-V Reconstruction Option is of comparable type and substantially equivalent to GE Veo Reconstruction Option and ASiR reconstruction option, the legally marketed devices described in this section above.

Verification, Bench and Clinical testing show that the GE ASiR-V Reconstruction Option provides equivalent or better performance (no loss of diagnostic quality, equivalent or improved LCD, equivalent or decreased image noise) compared to Filtered Back Projection. Product development and testing has demonstrated that no adverse effects or new questions of safety or effectiveness have been introduced.

The modifications are associated with the reconstruction software technology, image quality and dose reduction claims with quantitative values, evaluation methods such as model observer study with MITA LCD Phantom for LCD and availability with multiplatform CT scanners. ASiR-V has fundamentally the same intended use and indications for use as Veo.

The ASiR-V Reconstruction Option is the next generation of ASiR and leverages some of the design features of Veo. ASIR-V has been tested to show substantial performance improvements to conventional filtered back projection.

The substantial equivalence was also based on software documentation for a "Moderate" level of concern device.

Based on the above comparison and the successful testing, as well as the evaluation of sample clinical images, GE Healthcare believes that the GE ASiR-V Reconstruction Option is as safe and effective, and performs in a substantially equivalent manner to the predicate devices.

Summary of Additional Testing
In addition to the verification and validation testing successfully completed as required by GE Healthcare's quality system, additional engineering testing was performed to provide the requisite data to substantiate performance claims, and ultimately substantial equivalence. Sample clinical images were also provided.

Bench Testing (Non clinical)
Objective image quality testing was conducted for each claim. The CT scan data was reconstructed by both filtered back-projection and the ASiR-V reconstruction option for comparison.

To evaluate for the performance of low contrast detectability (LCD) improvement and dose reduction potential, a model observer study was conducted using the MITA IQ LCD phantom. Low contrast objects from the MITA phantom were imaged multiple times with several different GE CT scanners. In this study, a model observer analysis tool was applied to generate Receiver Operating Characteristic (ROC) curves and Area under ROC (AUC) values. AUC and SNR values were used to compare the detectability of low contrast pins of various diameters in the phantom from different reconstruction algorithms. The methods and phantom stem from work of the FDA-MITA IQ task force. In order to gain statistical confidence in the detectability, measurement for each contrast object, multiple scans, and regions of interests (ROIs) were required. The resulting data confirmed the lower dose and improved LCD using the ASiR-V Reconstruction Option. To evaluate for the performance of image noise reduction and high contrast spatial resolution improvement, the corresponding tests were conducted using phantoms and

more traditional CT image analysis methods. To evaluate for the performance of artifact reduction, the GE used an appropriately designed body size oval phantom that incorporated features to cause streak artifacts in clinical scenarios. Artifacts were measured and compared between FBP and ASiR reconstruction option.

In summary, ASiR-V may enable lower radiation dose by **50% to 82%** at the same image quality; and improve low contrast detectability by **59% to 135%** at the same dose; and reduce image noise up to **91%** at the same dose; and improve spatial resolution up to **2.07X (107%)** at same image noise; and possesses the capability of low signal artifact reduction such as streak artifact, relative to filtered back-projection, as demonstrated through phantom-based tests. Dose reduction and low contrast detectability were assessed using head and body protocols with multiple dose levels based on a model observer study. Image noise reductions, spatial resolution improvement, capability of low signal artifact reduction were assessed using protocols with multiple dose levels. All metrics tested on phantoms.

Sample Clinical Image Evaluation
As a demonstration of performance of the ASiR-V Reconstruction Option, a set of sample images from total 96 patient exams from three different GE CT platforms were provided along with a retrospective clinical read of diagnostic image quality. Each raw patient exam was reconstructed with each of two algorithms (FBP and ASiR-V), and a total of 192 clinical images, across anatomies were read by four radiologists. The four readers rated the diagnostic image quality (IQ) assessment using a 5-point Likert scale for 192 images randomly. After the evaluation with a Likert score, the total score of each recon algorithm is compared. The results demonstrated the clinical diagnostic quality of the ASiR-V images across various CT platforms and patient anatomies.

Conclusion:
ASiR-V may simultaneously enable;
- lower dose reduction by **50% to 82%** at the same image quality[1+];and
- low contrast detectability improvement by **59% to 135%** at the same dose[+] ;and
- image noise reduction up to **91%** at the same dose[+];and
- spatial resolution improvement up to **2.07X (107%)** at same image noise[+];and
- capability of low signal artifact reduction such as streak artifact [+]

relative to filtered back-projection, as demonstrated though phantom based tests.

Note:
[1] *Image quality as defined by low contrast detectability.*
[+] *In clinical practice, the use of ASiR-V 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. Low Contrast Detectability (LCD), Image Noise, Spatial Resolution and Artifact were assessed using reference factory protocols comparing ASiR-V and FBP. The LCD measured in 0.625 mm slices and tested for both head and body modes using the MITA CT IQ Phantom (CCT183, The Phantom Laboratory), using model observer method.*

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Based on the above consideration, GE Healthcare believes that the GE ASiR-V
Reconstruction Option is as safe and effective, and performs in a substantially
equivalent manner to the predicate device(s).

March 25, 2014

GE Medical Systems, LLC
% Huy Doan
Regulatory Affairs Director, MI&CT
3000 N. Grandview Blvd.
WAUKESHA WI 53188

Re: K133640
     Trade/Device Name: ASiR-V Workstation
     Regulation Number: 21 CFR 892.1750
     Regulation Name: Computed tomography x-ray system
     Regulatory Class: II
     Product Code: JAK
     Dated: December 24, 2013
     Received: January 22, 2014

Dear Huy Doan:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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

Janine M. Morris
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K133640

Device Name
ASiR-V

Indications for Use *(Describe)*

The ASiR-V Reconstruction Option is intended to produce cross-sectional images of the head and body by computer reconstruction of X-ray transmission data taken at different angles and planes, including Axial, Helical (Volumetric), and Cardiac acquisitions for all ages.

When used, it allows for an alternate reconstruction method designed to reduce image noise and streak artifact, increase resolution and improve low contrast detectability in images produced using raw Computed Tomography data from the GE CT scanner. The ASiR-V Reconstruction Option can be used to reduce noise in images and also to reduce the dose required for diagnostic CT imaging, including scans of the head, chest, heart, abdomen and pelvis. The ASiR-V Reconstruction Option may also improve the image quality of low dose non-diagnostic Filtered Back Projection images such that they become diagnostic.

ASiR-V reconstruction option is for use with the GE CT Scanners.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*