III. Summary of Safety and Effectiveness

A. Applicant

Name:	MedCom GmbH
Address:	12 Rundeturmstrasse Darmstadt, HE 64283 Germany

B. Device

Trade name:	VeriSuite
Common name	Patient position verification system
Classification name:	System, Radiation Therapy,Charged-Particle, Medical
Classification Number:	892.5050
Classification:	Class II
Product code:	LHN

C. Device Trade Name

VeriSuite also marketed as
VeriSuite 1.8 and
VeriSuite-Particle and
VeriSuite-Particle 1.8

D. Predicate device

Device trade name:	VeriSuite 1.6
510(k) number:	K080742
Company name:	MedCom GmbH
Classification Number:	892.5050
Classification:	Class II
Product code:	LHN

X-Ray Generator, Sedecal SHF 835

Device trade name:	
Classification name:	Generator, High Voltage Xray, Diagnostic
Classification Number:	892.1700
Classification:	Class I Exempt
Product Code:	IZO
Manufacturer	
Registration Number:	9617251

X-Ray Tubes, Varian A277 / A272

Classification name:	Assembly, Tube, Housing X-ray, Diagnostic
Classification Number:	892.1700
Classification:	Class I Exempt
Product Code:	IZO
Manufacturer	
Registration Number:	1717855

Flat Panel Digital Imager, Varian PaxScan 4030E

Classification name:	Solid State X-ray Imager
Classification Number:	892.1630
Classification:	Class II
Product Code:	MQB
510(k) Number:	-

Collimator, Ralco 302

Classification name:	Device, Beam Limiting, X-ray Solid State X-ray Imager
Classification Number:	892.1610
Classification:	Class II
Product Code:	KPW
510(k) Number:	K946320

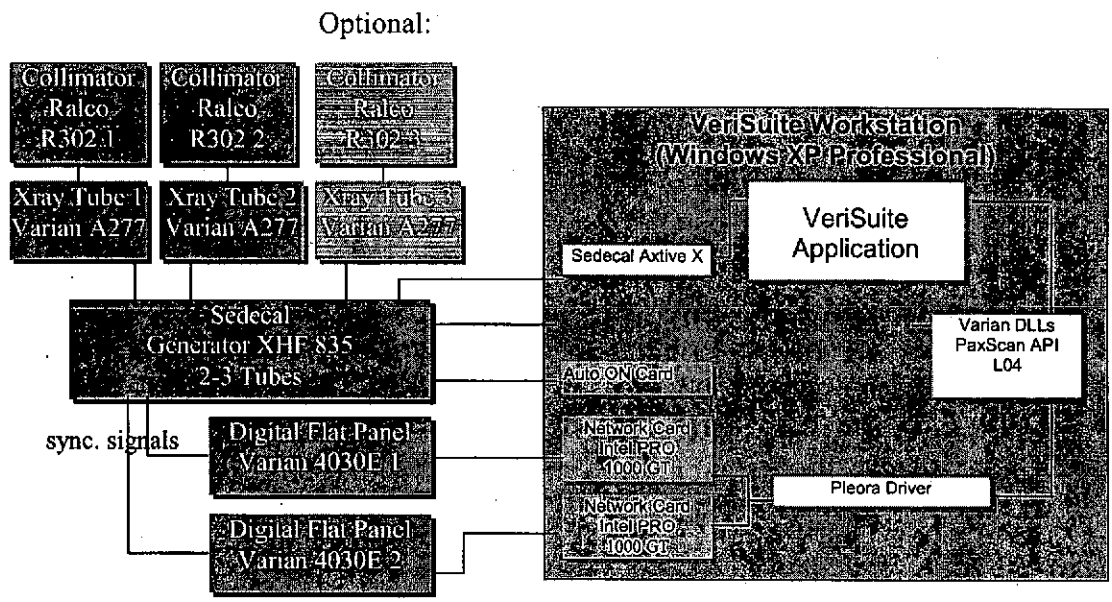
E. Description

VeriSuite is an image processing system for verification and correction of the patient position during a radiation therapy treatment. The verification or correction is performed by a comparison of X-ray images that are acquired during the treatment with DRRs (digital reconstructed radiographs) calculated from a CT image series of the patient and information from the radiation therapy planning. The correction can also be based on fiducial, radio-opaque markers that are implanted in the patient.

VeriSuite is a system of devices consisting of the VeriSuite software and a number of hardware devices:

- Beam limiting collimator device (Ralco 302)
- X-ray generator (Sedecal XHF 835)
- X-ray tubes (Varian A277 or A272)
- Flat panel digital imager (Varian 4030E

All these hardware devices are legally marketed in the US as listed in previous section D.



System Overview

F. Intended Use

VeriSuite is an active therapeutic medical device for verification of the patient position and calculation of a correction vector for the treatment of tumors during a radiation therapy with photons, electrons (from a linear accelerator) or particles (protons, heavy ions).

The VeriSuite system calculates digitally reconstructed radiographs (DRRs) based on a high-resolution CT data set for a treatment position. With these DRRs and X-ray images acquired during the performance of the position verification procedure a correction vector for the patient position can be calculated. An authorized person must evaluate the correctness of the calculation and approve the result for further usage.

The system shall only be used after correct installation in appropriate treatment rooms by trained personnel. Legal regulations especially regulation for the operation of X-ray devices must be regarded.

VeriSuite must not be used for diagnostic purposes

G. Summary of Technical Considerations

VeriSuite is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

SEP 18 2009

Mr. Stefan Walter
Quality Manager
MedCom GmbH
Rundeturmstrasse 12
Darmstadt, Hessen 64283
GERMANY

Re: K092653
Trade/Device Name: VeriSuite
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: LHN/IYE
Dated: August 20, 2009
Received: August 28, 2009

Dear Mr. Walter:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

VIII. Indications for Use Statement

510(k) Number (if known): K092653

Device Name: VeriSuite

The VeriSuite patient position verification system is used for verification and correction of the patient's position during a radiotherapy treatment with external beams or charged particles. It is based on stereoscopic X-ray images and DRRs calculated from a CT image series of the treatment region of the patient and information from the treatment planning.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092653