V. 510(k) Summary of Safety and Effectiveness

APR 0 9 2014

A. Submitter

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Date:	December 20, 2013

B. Device

Trade Name:	VeriSuite also marketed as VeriSuite 1.8 and VeriSuite-Particle and VeriSuite-Particle 1.8	
Common name:	Patient position verification system	
Classification:	Regulatory Class:	II
	Product Code:	LHN / Classification Name: system, radiation therapy, charged-particle, medical
	Subsequent Product Code:	IYE / Classification Name: accelerator, linear, medical
	CFR Section:	892.5050
	Panel:	Radiology

C. Predicate Devices

Device trade name:	VeriSuite 1.8
510(k) number:	K092653
Company name:	MedCom GmbH
Classification Number:	892.5050
Classification:	Class II
Product code:	LHN

Subsequent code: IYE

Device trade name: EXACTRAC 5.5 / ExacTrac X-RAY 6D
510(k) number: K072506
Company name: BRAINLAB AG
Classification Number: 892.5050
Classification: Class II
Product code: IYE

D. Reason for Submission

Changed device: Fluoroscopy extension

E. Standards

1. IEC 61217 (2008), Radiotherapy equipment - Coordinates, movements, and scales Consolidated Edition 1.2. (Radiology)

2. ISO 14971:2007, Medical devices - Application of risk management to medical devices. (General I (QS/RM))

3. IEC 62304 First edition 2006-05, Medical device software - Software life cycle processes. (Software/Informatics)

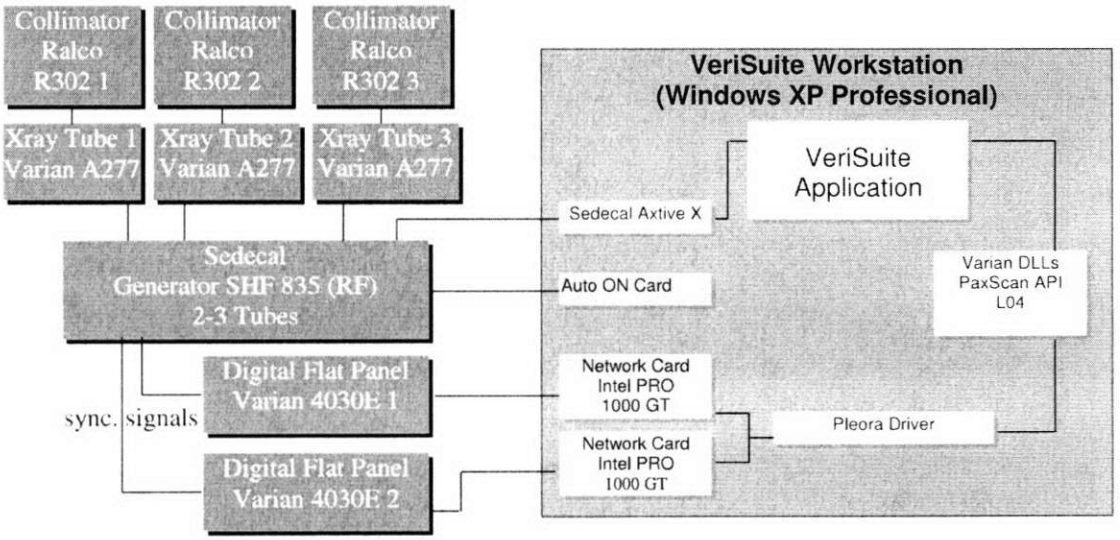
F. Description

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.
With the fluoroscopy extension it is possible to observe the position of the patient and the treatment area during the treatment. Mainly the movements of the patient caused by breathing are in the focus. This information can be used to interrupt the treatment by the user.

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

Device	Type	510(k) / registration number
Beam limiting collimator device	Ralco 302	K946320
X-ray generator	Sedecal SHF 835 (RF)	9617251
X-ray tubes	Varian A277 or A272	1717855
Flat panel digital imager	Varian 4030E,	K024147

All these hardware devices are legally marketed in the US as listed in the table above.



System Overview

G. 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.
The VeriSuite® system with fluoroscopy extension provides the possibility to a medical user to observe the position of the patient and the treatment area during the treatment, mainly the movements of the patient caused by breathing. This information can be used to interrupt the treatment.
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.

H. Technological Comparison to Predicate Devices

The changed device VeriSuite 1.8 (build number B641.4, subject of this submission) is substantially equivalent to the predicate device VeriSuite 1.8 (K092653) except the fluoroscopy extension.

The fluoroscopy extension of VeriSuite is substantially equivalent to the fluoroscopy functionality of the predicate device EXACTRAC 5.5 / ExacTrac X-RAY 6D (K072506) in terms of intended use and technology.

In contrast to EXACTRAC 5.5, VeriSuite does not support optical prepositioning and internal respiratory gating signal display. Because of the reproducibility of the patient preposition due to the fixation of the patient, optical prepositioning is not required in the VeriSuite environment. Respiratory gating can be displayed using external devices.

Minor differences exist in the hardware used in terms of resolution of the flat panels, x-ray image and pixel size, which are higher for VeriSuite.

Refer to section XII for a detailed predicate device comparison.

I. Non-clinical Performance Data

Non-clinical verification and validation software tests were conducted to confirm that VeriSuite 1.8 with fluoroscopy meets its intended use and is safe and effective. See section XVI.I for details.

J. Conclusion

Based on the information provided in this Premarket Notification MedCom concludes that VeriSuite 1.8 with fluoroscopy extension is as safe and effective and substantially equivalent to the predicate devices described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 3, 2014

MedCom GmbH
% Mr. Luca Salvatore
Quality Manager
Rundeturmstrabe 12
64283 Darmstadt
GERMANY

Re: K133914
Trade/Device Name: VeriSuite 1.8, VeriSuite-Particle 1.8, VeriSuite, VeriSuite-Particle
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: LHN
Dated: January 6, 2014
Received: January 8, 2014

Dear Mr. Salvatore:

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,

Michael D. O'Hara 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)*

K133914

Device Name
VeriSuite

Indications for Use *(Describe)*

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.

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)*

Michael D. O'Hara

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."