September 21, 2018

MEDCOM GmbH
% Mr. Johannes Messow
Quality Manager
11 Dolivostrasse
DARMSTADT 64293
GERMANY

Re: K181789
Trade/Device Name: VeriSuite
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: LHN, IYE
Dated: June 22, 2018
Received: July 5, 2018

Dear Mr. Johannes:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for
Robert A. 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)*
K181789

Device Name
VeriSuite

Indications for Use *(Describe)*
VeriSuite is an image processing software 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).

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.

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.

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

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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."

III. 510(k) Summary of Safety and Effectiveness

A. Submitter

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Contact:	Mr. Johannes Messow jmessow@medcom-online.de
Date:	June 22, 2018

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 VERO
510(k) number:	K122451
Company name:	BRAINLAB AG
Classification Number:	892.5050
Classification:	Class II
Product code:	IYE

D. Reason for Submission

Changed device: 3D3D matching module

E. Standards

VeriSuite® meets the requirements of the following standards:

- *IEC 61217 Edition 2.0 2011-12, Radiotherapy equipment - Coordinates, movements, and scales Consolidated Edition 1.2. (Radiology)*
- *ISO 14971:2007 Second Edition 2007-03-01, Medical devices - Application of risk management to medical devices. (General I (QS/RM))*
- *IEC 62304 Edition 1.1 2015-06, 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 the current patient treatment position with a CT 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.

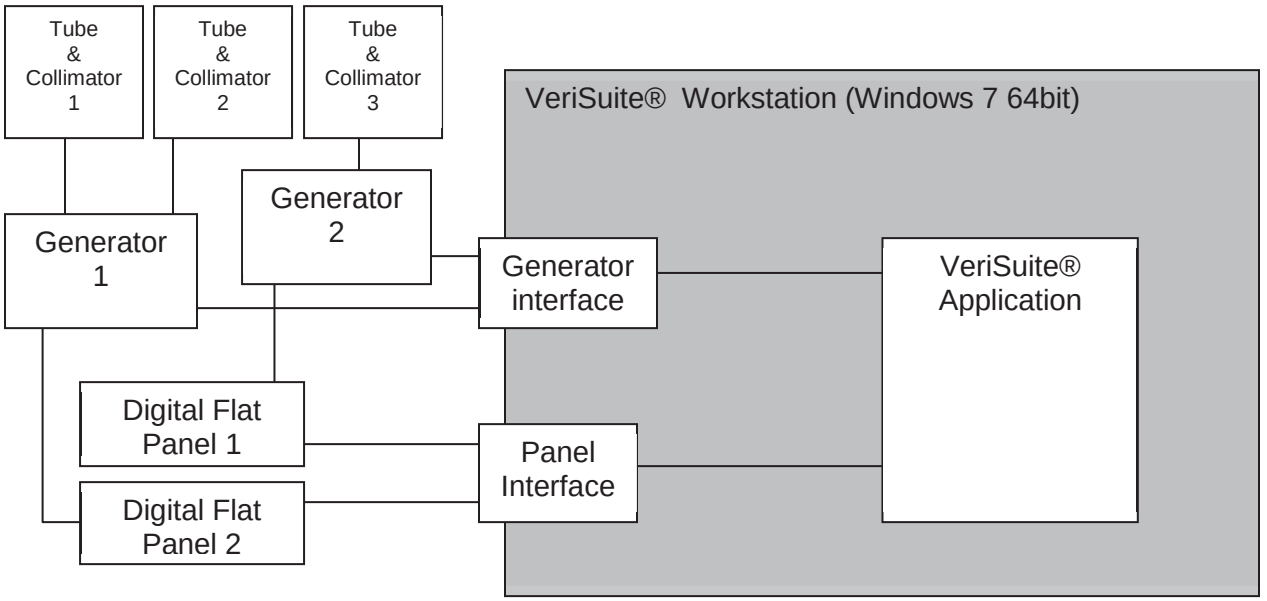
With the 3D3D extension it is possible to compare two CT volumes with each other. The positioning volume is received from the TRCS (i.e. from a second CT device located in the treatment room.)

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) X-Alliance EPS 45-80	9617251 510(k) exempt
X-ray tubes	Varian A277 or A272	1717855
Flat panel digital imager	Varian 4030E, Varian 4030D	K024147 K024147

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

System Overview



G. **Indications for Use**

VeriSuite is an image processing software 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).

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® 2.3 (build number B100.48, subject of this submission) is substantially equivalent to the predicate device VeriSuite® 1.8 (K133914) except the 3D3D extension.

The 3D3D extension of VeriSuite® is substantially equivalent to the 3D3D functionality of the predicate device EXACTRAC Vero (K122451) in terms of intended use and technology. EXACTRAC Vero uses CBCT reconstruction to get the positioning volume, while VeriSuite® receives the positioning CT via DICOM. The CT source in this case is a 3rd party CT scanner or a table mounted CBCT scanner.

In contrast to EXACTRAC Vero, VeriSuite® does not support optical prepositioning *or in-treatment* monitoring. Because of the reproducibility of the patient preposition due to the fixation of the patient, optical prepositioning is not required in the VeriSuite® environment. In-treatment monitoring is possible with fluoroscopic imaging.

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

Both EXACTRAC Vero and VeriSuite® use gantry mounted stereotactic x-ray imaging for 2D/3D positioning or a second CT volume. Images are taken with 2 dimensional receptors, including CBCT, not 1 dimensional lines. The images or volumes are used to calculate a correction vector and move the patient in the iso-center position for treatment.
Upper precision limits and corrected degrees of freedom are the same. The field of view in VeriSuite® is bigger than the one of EXACTRAC Vero, due to larger distances between tube and iso-center in the x-ray beamline. This should lead to similar or better results.

The usability and treatment workflow is very close to the existing 2D3D workflow in VeriSuite® B614.4, so that the user intuitively knows what to do and expect. The layout and tools are same or similar to the existing workflow.

I. Non-clinical Performance Data

Non-clinical verification and validation software tests were conducted to confirm that the 3D3D extension of VeriSuite® meets its intended use and is safe and effective.

Test have been performed with medical phantoms. Simulated patient data was used to perform the workflow and verify precision and robustness of the algorithm. The achieved results were within expected parameters.

Usability testing showed, that the user has no problem following the workflow. It is based on the existing 2D3D workflow, so that all the necessary information is located at the same place. Only the CT data representation changed, from a 2d rendering to a slice based volume visualization which therapists are used to from other machines. Measurement tools, fusion view, zoom, panning, rotation and radiotherapy structure set display did not change. The final result can only be approved, if all previous steps were successful.

The tested software is safe and useful in the process of proton therapy. Based on performed tests and feedback from VeriSuite® users in the EU (CE marked), the algorithmic robustness could be improved, as well as the precision of the CV.

J. Conclusion

Based on the information provided in this Premarket Notification MedCom concludes that the 3D3D extension of VeriSuite® is as safe and effective and substantially equivalent to the predicate devices described herein.

The risk analysis shows that the product is safe and the risk/benefit ratio is acceptable.

Risks identified with similar MedCom devices and similar marketed devices of other manufacturers were considered and included in the risk assessment of the 3D3D extension of VeriSuite®.
All identified risks were reduced by appropriate risk control measures to an acceptable level, also including risks which were evaluated as acceptable before any measures. The overall residual risk is acceptable. According to the intended use of the 3D3D extension of VeriSuite® , the users are medical professionals and familiar with patient position verification systems and have sufficient knowledge in that respective area. The overall probability of serious injury was therefore evaluated as "improbable".

The Clinical Evaluation shows that the system is effective and comparable to existing procedures.

No issues have been detected that would prevent the 3D3D extension of VeriSuite® to be used in the clinical environment. Data has been collected through literature search which indicates that the 3D3D extension of VeriSuite® is state of the art like other tools currently on the market and thus a focused clinical evaluation appears sufficient.