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

Medical Intelligence Medizintechnik GmbH
% Mr. Michael Wolff
Regulatory Affairs Manager
Robert-Bosch-Strasse 8
Schwabmunchen, 86830
GERMANY

March 4, 2015

Re: K143485
Trade/Device Name: iGUIDE 2.1
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: November 4, 2014
Received: December 8, 2014

Dear Mr. Wolff:

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.
Acting 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)*
K143485

Device Name
iGUIDE 2.1

Indications for Use *(Describe)*

The intended use of the device is the control of accurate patient positioning with assistance of a 3D Tracking System in a radiotherapy environment.

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.

Traditional 510(k)
510(k) Summary

iGUIDE 2.1

iGUIDE 2.1- 510(k) Summary

1.	Applicant	Medical Intelligence Medizintechnik GmbH
2.	Address	Robert-Bosch-Straße 8 86830 Schwabmünchen Germany
3.	Contact Person	Michael Wolff, +49 (0) 8232 9692 701
4.	Preparation Date	December 2nd, 2014
5.	Device Submitted	iGUIDE® 2.1 System
6.	Proprietary Name	iGUIDE® 2.1 System
7.	Common Name	iGUIDE® 2.1
8.	Classification Name	Accelerator, Linear, Medical (21 CFR 892.5050, Product Code IYE)
9.	Substantial Equivalence	The iGUIDE® 2.1 is substantially equivalent to the following currently marketed device: iGUIDE® System (K072079) iGUIDE® 2.1 is an advancement of the iGuide® System and has similar technological characteristics as the predicate device.
Device Description		The iGUIDE 2.1 System is a powered radiation therapy support assembly which provides patient positioning control prior to radiotherapy treatment. iGUIDE 2.1 System consists of the iGUIDE workstation with software, a tracking system, reference frame, calibration tool, isolation transformer, KVM Extender and monitors for the workstation and terminal. The iGUIDE software controls the combined working of the HexaPOD evo RT System components and provides status detection via the software GUI to the user. The HexaPOD evo RT System consists of iGUIDE and the HexaPOD evo RT Couchtop, a robotic patient-positioning platform with six degrees of freedom, which is cleared under K072898.
10.	Indications for Use	The intended use of the device is to control accurate patient

positioning with assistance of a 3D Tracking System in a radiotherapy environment.

11. Summary of Product Changes

- Compatibility with the Brainlab ExacTrac® V6.1 system
- Control of the Elekta Precise Treatment Table
- Enhanced usability and elimination of use errors through:
  - Automatic receipt of patient data
  - Use of Remote Automatic Table Movement interface; manual prepositioning function is no longer supported
  - Automated data transfer from XVI to iGUIDE & Sentinel to iGUIDE

12. Summary of Similarities

iGUIDE® 2.1 is similar to the predicate device in terms of:

- Intended use
- product components
- technological characteristics (regarding design, material, energy source)

13. Comparison with predicate device

Manufacturer	Medical Intelligence Medizintechnik GmbH	Medical Intelligence Medizintechnik GmbH
Device Name	iGUIDE 2.1 System	iGUIDE System
PreMarket Notification Number	Proposed	K072079
Indications for Use	The intended use of the device is to control accurate patient positioning with assistance of a 3D Tracking System in a radiotherapy environment.	The intended use of the device is to control accurate patient positioning with assistance of a 3D Tracking System in a radiotherapy environment.
Components	• Software • Tracking System • Workstation • Monitor • KVM Extender • Isolation Transformer • Reference Frame • Calibration Tool	• Software • Tracking System • Workstation • Monitor • KVM Extender • Isolation Transformer • Reference Frame • Calibration Tool
Protection Class	I B	I B

Traditional 510(k)
510(k) Summary

iGUIDE 2.1

Manufacturer	Medical Intelligence Medizintechnik GmbH	Medical Intelligence Medizintechnik GmbH
Device Name	iGUIDE 2.1 System	iGUIDE System
Software Safety Classification	C (Major Level of Concern)	C (Major Level of Concern)
Hardware Platform	Part of the HexaPOD evo RT System - consisting of HexaPOD evo Couchtop (K072898) and iGUIDE components (see below)	Part of the HexaPOD RT System - consisting of HexaPOD Couchtop (K071870) and iGUIDE components (see below)
Position control by 3D tracking System	yes	yes
HexaPOD evo RT Couch Top as treatment couch	yes	yes
Movement Control	yes	yes
Table Movement	Remote Automatic Table Movement	Manual prepositioning function
Accuracy of 3D Tracking System	0.35mm	0.35mm
Accuracy of total system (Treatment table + tracking system)	<1mm; CI95: <0,5mm	< 0.5 mm (translation) < 0.25° (rotation)
Receiving patient data	Automatic data transfer to iGUIDE	Manual data transfer to iGUIDE
Sending patient data	Automated data transfer from iGUIDE	Manual data transfer from iGUIDE
Enable switches	• Interrupts directly the power of the moving component • In control room and treatment room	• Interrupts directly the power of the moving component • In control room and treatment room
Interlock connection to Linac	Overrides the enable switch control	Overrides the enable switch control

14. Summary of Performance Testing

The Performance Testing is based on Benchmark Testing only.

Rationale: As the iGUIDE 2.1 is a positioning device which does not perform any treatment on its own but helps to position and re-position the patient, only physical parameters characterize the system (e.g. accuracy) and give information about substantial equivalence of the modified system compared to the predicate (unmodified) system which was cleared under K072079.

The results of the verification and validation and bench testing demonstrate that the iGUIDE 2.1 System with the extended compatibility and improved usability satisfies the intended use as described above and supports the claim of substantial equivalence.