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

May 20, 2015

Eckert & Ziegler BEBIG GmbH
% Mr. Hub van de Bergh
Consultant QA & RA Medical Devices
Traceability QA & RA Services
Muurzwaluw 30
3905 RZ Veenendaal
THE NETHERLANDS

Re: K141900
Trade/Device Name: SagiPlan
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide Applicator system
Regulatory Class: II
Product Code: MUJ
Dated: April 24, 2015
Received: April 27, 2015

Dear Mr. van de Bergh:

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)
K141900

Device Name
SagiPlan

Indications for Use (Describe)
SagiPlan is a Brachytherapy Treatment Planning System used by medical professionals.
SagiPlan is used for the creation of treatment plans for remote afterloader based HDR brachytherapy.
SagiPlan will calculate a proposed treatment course based on imported clinical images and other user entered data.
SagiPlan also supports the evaluation of clinical images in calculating the local and global doses to organs at risk and target volumes. SagiPlan especially supports the SagiNova Brachytherapy Remote Controlled Afterloading Device from Eckert & Ziegler BEBIG GmbH.

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.

7 510(k) Summary as required by 21 CFR 807.92

7.1 Submitter of 510(k)

510(k) owner's name : Eckert & Ziegler BEBIG GmbH
address : Robert-Rössle-Strasse 10
13125 Berlin
Germany
phone : +49 30 94 10 84 119
fax : +49 30 94 10 84 112

company's contact person : Michel Lafuente

For this 510(k) submission
name of contact person (consultant) : Hub van de Bergh
e-mail : hubvandebergh@gmail.com

date the summary was prepared : June 30, 2014

7.2 Device: SagiPlan

name of the device / trade or proprietary name: **SagiPlan**
common or usual name: Brachytherapy Treatment Planning System
classification name: Remote controlled radionuclide applicator system
(per 21 CFR section 892.5700 Product code MUJ)

7.3 Legally Marketed Device(s)

SagiPlan can be shown to be substantial equivalent to the legally marketed predicate device cited in the table below.

Device	Manufacturer	510(k) #
HDRplus	Eckert & Ziegler BEBIG GmbH	K123263

7.4 Description of the Device

7.4.1 SagiPlan

SagiPlan is a software package which runs on a Windows – based PC and is used by medical professionals to create a radiation therapy plan based on imported medical images and the input manually entered by the operator.
The software offers tools to enhance imported images and offers contouring of the planned target volume and organs at risk. The isotopes used in the calculations match those which are normally used in High Dose Rate (HDR) remote afterloaders.
The main use of SagiPlan is to calculate the required dwell times at the predetermined dwell positions in a uniform way so that the Planning Target Volume (PTV) is treated with the prescribed dose while sparing the Organs At Risk (OAR).
SagiPlan can reconstruct one or more applicators.
Based on the contoured target volume and the prescription dose, SagiPlan will calculate the optimal dose distribution for the tumor volume. Evaluation tools are available to qualify the proposed treatment. The therapy planning is then transferred from the SagiPlan software to the brachytherapy afterloader radiation device.
The SagiPlan software is intended to be used with the SagiNova and the MultiSource Brachytherapy Remote Controlled Afterloading Devices from Eckert & Ziegler BEBIG GmbH.

The SagiPlan System comprises subjoined listed subsystems:

- Personal Computer
  to execute the SagiPlan software.
- Monitor
  to visualise the treatment planning process.
- Keyboard
  to enter treatment data.
- Mouse
  to select objects on the screen

The PC is used to execute the SagiPlan software and runs under Windows 7. The hard disk stores patient data and the built in DVD-RW is used for making backup of the Patient Data. The PC can be connected to the hospital network to import Patient Image Data.

7.4.2 Accessory: Film Scanner

The Film Scanner allows the user to read an X-Ray image to present it on the screen to visualise the brachytherapy applicator implant.

7.4.3 Accessory: Printer

The Printer allows for hard copy of the patients treatment plan and other stored data.

7.4.4 Accessory: Pen Tablet

The Pen Tablet acts as an alternative replacement for the mouse enabling the user to outline more accurately and faster a contour on the monitor.

7.4.5 Accessory: Touch Panel

The Touch Panel acts as an alternative replacement for the mouse enabling the user to outline more accurately and faster a contour on the monitor.

7.5 Intended use of the Device

SagiPlan is used for the creation of treatment plans for High Dose Rate remote afterloader based brachytherapy. SagiPlan calculates a proposed treatment course based on imported clinical images and other user entered data. SagiPlan also supports the evaluation of clinical images in calculating the local and global doses.

7.6 Technological characteristics of device compared to the predicate device

The SagiPlan Brachytherapy Treatment Planning System has the same technological characteristics as the legally marketed predicate device from which it is derived and listed above which is cleared under 510(k) #K123263.

The SagiPlan technology is based on a computer system, a monitor for data visualisation, keyboard and mouse for data entry. A film scanner is used to read available medical images. Optionally a frame grabber may be used with SagiPlan for capturing video images electronically.
SagiPlan is designed to run in a Microsoft Windows run-time environment.

7.7 Substantial Equivalence

From the discussion in previous paragraphs it can be concluded that the SagiPlan Brachytherapy Treatment Planning System has the same technological characteristics compared to the legally marketed predicate device indicated in section 7.3.

The differences between SagiPlan and predicate device do not concern the basic principle of operation nor does it adversely affect the safety or effectiveness of the device.

The intended use of SagiPlan and predicate device are the same.

The conclusion is that SagiPlan is substantial equivalent to the legally marketed predicate device.

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