K 123263

Eckert & Ziegler

APR 0 4 2013

6 510(k) Summary as required by 21 CFR 807.92

6.1 Submitter of 510(k)

510(k) owner's name	:	Eckert & Ziegler BEBIG GmbH
address	:	Robert-Rössle-Strasse 10 13125 Berlin Germany
phone	:	+49 30 941084130
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name of contactperson	:	Hub van de Bergh
e-mail	:	hubvandebergh@gmail.com
date the summary was prepared	:	August 10, 2012

6.2 Device: HDRplus

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

6.3 Legally Marketed Device(s)

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

Device	Manufacturer	510(k) #
Flexiplan	Isodose Control B.V.	K091145

6.4 Description of the Device

6.4.1 HDRplus

HDRplus 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 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) and Pulsed Dose Rate (PDR) remote afterloaders.
The main use of HDRplus 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).
HDRplus can reconstruct one or more applicators. Based on the contoured target volume and the prescription dose, HDRplus 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 HDRplus software to the brachytherapy afterloader radiation device.
The HDRplus software is intended to be used with the Multisource and GyneSource Brachytherapy Remote Controlled Afterloading Devices from Eckert & Ziegler BEBIG GmbH.

The HDRplus System comprises subjoined listed subsystems:

- Personal Computer
  It executes the HDRplus 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 HDRplus software and runs under Windows XP Professional or 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.

6.4.2 Accessory: Film Scanner

The Film Scanner allows the user to scan in an X-Ray image to present it on the screen to visualise the implant.

6.4.3 Accessory: Printer

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

6.4.4 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.

6.4.5 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.

6.5 Intended use of the Device

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

6.6 Technological characteristics of device compared to the predicate device

The HDRplus Brachytherapy Treatment Planning System has the same technological characteristics as the legally marketed predicate device listed above which is cleared under 510(k) #K091145.

The HDRplus technology is based on a computer system, a monitor for data visualisation, keyboard and mouse for data entry. Optionally a frame grabber may be used with HDRplus for capturing video images.

6.7 Substantial Equivalence

From the discussion in previous paragraphs it can be concluded that the HDRplus Brachytherapy Treatment Planning System has the same technological characteristics compared to the legally marketed predicate device indicated in section 6.3.

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

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

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 4, 2013

Hub van de Bergh
Consultant
ECKERT & ZIEGLER BEBIG GMBH
C/O TRACEABILITY QA & RA SERVICES
MUURZWALUW 30, 3905 RZ VEENENDAAL
NETHERLANDS

Re: K123263
Trade/Device Name: HDRplus & Add in prostate Module for HDRplus
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: MUJ
Dated: March 15, 2013
Received: March 20, 2013

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 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,

for

Janine M. Morris, M.S.
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123263

Device Name: HDRplus

Indications for Use:

HDRplus is a Brachytherapy Treatment Planning System used by medical professionals. HDRplus is used for the creation of treatment plans for remote afterloader based HDR and PDR brachytherapy. HDRplus will calculate a proposed treatment course based on imported clinical images and other user entered data. HDRplus also supports the evaluation of clinical images in calculating the local and global doses to organs at risk and target volumes. HDRplus especially supports the Multisource and Gynesource Brachytherapy Remote Controlled Afterloading Devices from Eckert & Ziegler BEGIB GnbH.

Prescription Use x AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K123263