MedCom GmbH
% Mr. Johannes Messow
Quality Manager
Dolivostrasse 11
Darmstadt, Hessen 64293
GERMANY

March 27, 2018

Re: K180308
Trade/Device Name: Prelude
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ, LHO
Dated: January 29, 2018
Received: February 2, 2018

Dear Mr. Messow:

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.

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.

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,

Michael D. O'Hara For

Robert 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)*
K180308

Device Name
Prelude

Indications for Use *(Describe)*
The Prelude Planning Software for the electron beam IORT treatment can be used for any malignant and benign tumor. For Prelude no limitation is given to the patient population. Local/Regional recommendations or guidelines may indicate patient who will benefit from IORT more than from other treatment modalities.
In general, since Prelude is tailored for the planning with the Mobetron®, it can be used for IORT treatment planning, if a patient is prescribed to be treated with the Mobetron®.

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:	Jan 29, 2018

B. Device

Trade Name:	Prelude	
Common name**:**	IntraOp Prelude	
Classification:	Regulatory Class:	II
	Product Code: Classification Name:	MUJ System, Planning, Radiation Therapy Treatment
	CFR Section:	892.5050
	Panel:	Radiology

C. **Predicate Devices**

Device trade name:	Radiance
510(k) number:	K171885
Company name:	GMV
Classification Number:	892.5050
Classification:	Class 2
Product code:	MUJ

Device trade name:	Track-it
510(k) number:	510(K) Exempt
Company name:	PTW-FREIBURG
Classification Number:	892.1940
Classification:	Class I
Product code:	LHO

D. **Reason for Submission**

New device application

E. **Standards**

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

2. IEC 62304:2006/AMD1:2015, Medical Device Software - Software Life Cycle Processes. (Software/Informatics)

3. IEC 62083:2009 – Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems

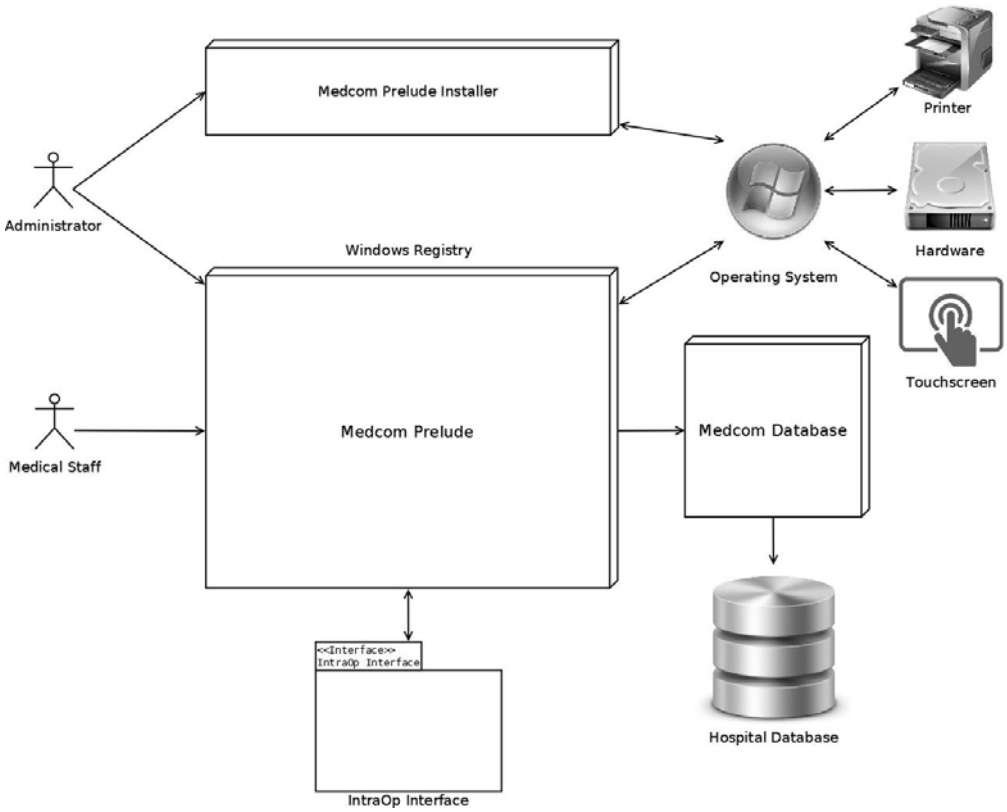
F. **Description**

Prelude software supports the IORT treatment workflow. Dosimetric measurement data of the radiation device can be displayed by selecting the machine parameters. Upon that information the user can easily plan the treatment and the software calculate the required parameters for the IORT devices.
For quality assurance the machines parameters can be recorded and visualized.
For the calculation of the output factors or the monitor units either the IAEA or AAPM protocol is followed.
The software is intended to be used by medical professionals in the area of radiation therapy.

The main purpose is to plan the technical parameters required to perform an electron beam IORT to treat both malignant and benign tumors

Examples of compatible devices are:

Device	Type	510(k) / registration number
Planning System, QA software	GMV Radiance	K171885
	PTW – Track It	510(k) Exempt



System Overview

The Prelude software is developed in Microsoft Visual Studio in programming language **C**. As main architectonical style is a module concept. Each module consists of a standard and predefined set of function for data initialization, parameter-file handling, UI creation and handling.

The Prelude Database Server is written in **C/C++** using Microsoft Foundation Classes (MFC) and *an* SQL*ite database.*

For details of the Software Architecture refer to:
003_MC.5078.TDC.0001.System_Architecture

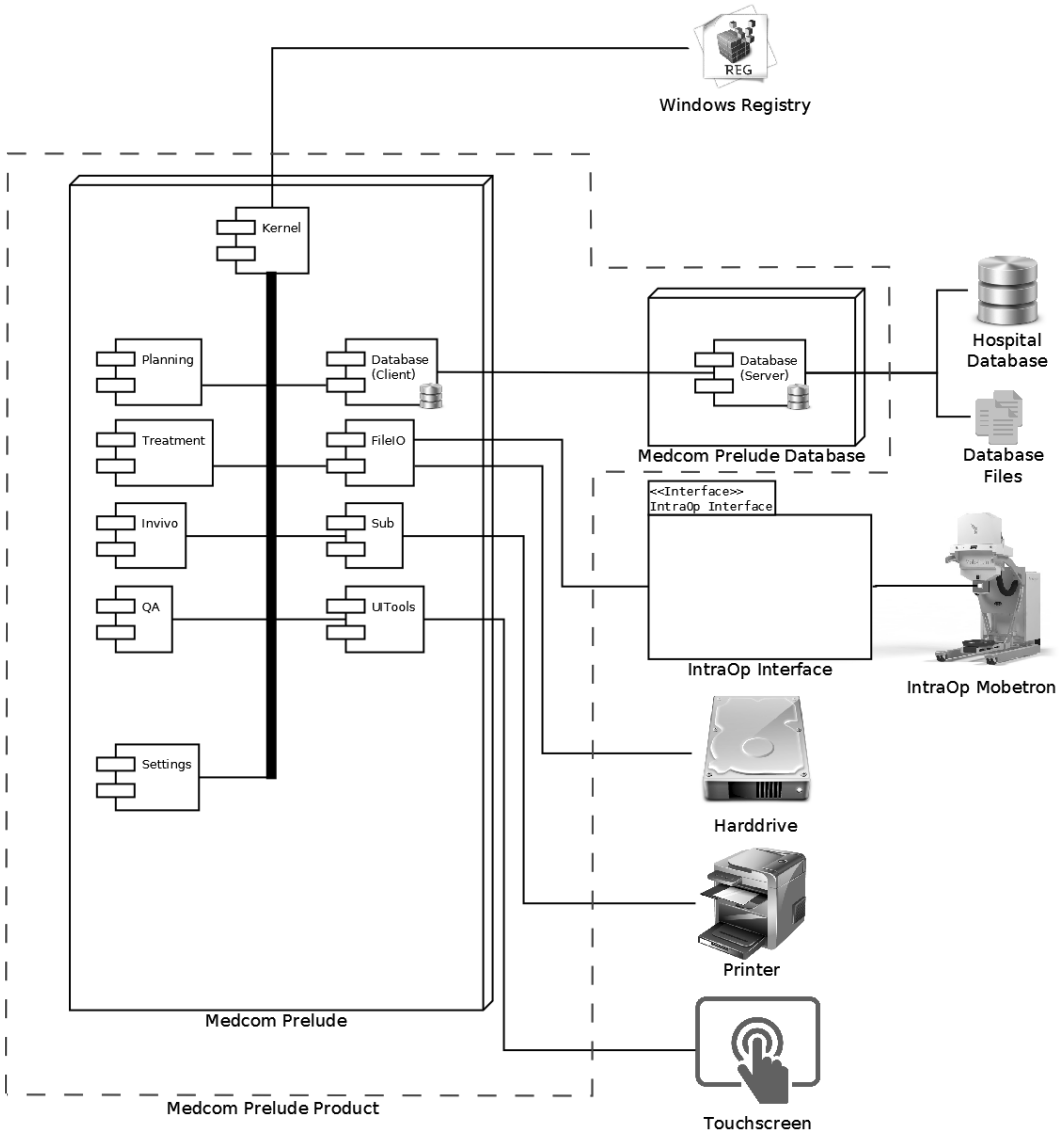


Figure 1: Architecture Overview

*Figure **1*** shows an overview of the program and it´s modules. The blue line marks the MedCom Products (Prelude and its Database Server) and their interaction with internal/external devices.

G. **Intended Use**

The Prelude software supports intra-operative radiation therapy workflows with intra-operative radiation devices like IntraOp® Mobetron®.
It assists to find product specific machine parameters for treatment and can send those proposals to the intra-operative radiation device.
The machine parameters are not intended to be used for direct control for the radiation device.

Dose distribution visualizations are based on measured beam data and tissue inhomogeneities are not taken into account, the resulting dose distribution for anatomic locations in close proximity to bone and lung (or other tissue of high or low density) may differ from the presented visualization.

Machine Output Quality can be visualized and recorded over time for quality assurance.

The use of Prelude is restricted to medical professionals of radiation therapy.

H. **Indications for Use**

The Prelude Planning Software for the electron beam IORT treatment can be used for any malignant and benign tumor.
For Prelude no limitation is given to the patient population. Local/Regional recommendations or guidelines may indicate patient who will benefit from IORT more than from other treatment modalities.
In general, since Prelude is tailored for the planning with the Mobetron®, it can be used for IORT treatment planning, if a patient is prescribed to be treated with the Mobetron®.

Prelude is a prescription device.

I. Technological Comparison to Predicate Devices

The device Prelude is substantially equivalent to the following predicate devices:

K171885	GMV Radiance
510(k) Exempt	PTW Track It

The predicate device Radiance (GMV) has similar main functionalities and characteristics as Prelude for the planning part of an IORT treatment.
Both devices provide a visualization of the dose distributions in the treatment field. Both systems are based on measured dosimetric characteristic of the beam. Monitor Units calculation in both systems is based on Percentage Depth Dose curve along central axes of the beam.
Those are the core functions of both systems and they are similar.

Prelude, unlike Radiance, does not use 3D patient data (e.g. CT scans) so performed calculations are based on homogenous medium (i.e. water) and material heterogeneities are not taken into account. Since, IORT intends to treat mainly soft tissue (which, from the radiation perspective, is equivalent to water) water-based calculation of dose distribution and MUs provides very good approximation of clinical situation and the planning can be done faster.
Anyhow in an IORT treatment room, there is often no possibility to acquire CT scans during the treatment. Thus, planning on pre-operative images, like it is done with Radiance, is also an approximation of the treatment region during the surgery. This dissimilarity in the functionality of both systems should be considered insignificant.

The predicate device Track-It® (PTW) and Prelude are adequately similar concerning management of Quality Assurance of Electron Beam devices and analyzing QA results recorded over time. Both devices enable detailed tracking of QA measurements in order to analyze trends occurring in the machine functionality. The devices can be adapted to common QA protocols for medical accelerators (e.g. AAPM guidelines or IAEA protocols). QA sessions can be recorded offline and synchronized once a server connection is reestablished. It is possible to track data of multiple devices separately. Prelude and Track-It® have a client/server architecture with a server-side database that can be queried with custom filter conditions.

Prelude does not support multiple types of medical accelerator and currently only supports data tracking for electron beams, which are generated by the Mobetron®. Prelude is not customizable to the same extent as the general-purpose QA data tracking tool Track-It®. These dissimilarities between Prelude and Track-It® are insignificant since Prelude is tailored and intended only for the use in combination with the Mobetron® accelerator. Hence, limitations in beam energies and accelerator types pose no limitations of safety, performance and effectiveness but are intended design decisions.

J. **Non-clinical Performance Data**

Non-clinical verification and validation software tests were conducted to confirm that the Prelude System meets its intended use and is safe and effective.

Tests have been performed with dosimetric measurement data from a Mobetron® device. Clinical patient data was simulated and achieved results led to expected parameters for a treatment of the simulated input data.

Usability testing showed, that the user could successfully create a treatment plan, defining all necessary treatment parameters (beam energy, applicator diameter, prescribed dose, etc.). It was absolutely understandable and clear for the user, where to enter each parameter and how these parameters impact the dose distribution visualized by the software. The workflow offered by the software requires all crucial parameters to be entered before the Monitor Units can be calculated and the treatment plan can be approved.
The complete treatment plan was successfully approved by the user (with sufficient rights) and saved into the database. User was able review and confirm all treatment parameters by verifying the report created by the software and by accessing the plan from the database.

Based on extensive testing, briefly summarized above, one can conclude that all the usability goals were met. Tested software does not create any new risk to the intraoperative radiotherapy procedure performed with the Mobetron®. It is safe and usable in the clinical environment.

The tested software is safe and useful in the process of Intraoperative Radiotherapy. Based on performed tests and feedback provided by Mobetron users and other experts in that field, the IORT treatment delivery could be optimized due to fast dose distribution visualization with energy mixing.
Integration of all patient and treatment data into one software platform and one central database makes the data analysis and reporting very convenient and efficient. What is more, Quality Assurance management features allow streamlining workflow and tracking equipment performance.
It might be concluded that the software improves efficiency of IORT procedure by integrating various treatment planning and QA tools into a single, intuitive platform.

K. **Conclusion**

Based on the information provided in this Premarket Notification MedCom concludes that Prelude system 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 Prelude. For an effective identification, estimation and evaluation of risks, the risk assessment team included application specialists and a medical expert besides the development team and quality managers with risk management experience.

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 Prelude, the users are medical professionals and familiar with IORT treatments 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 Prelude to be used in the clinical environment. Data has been collected through literature search which indicates that Prelude is state of the art like other tools currently on the market and thus a focused clinical evaluation appears sufficient.