Micropos Medical AB
% Hanna Syren
Director QA, Regulatory and Clinical Affairs
Adolf Edelsvärds gata 11
Gothenburg, SE414 51
SWEDEN

September 2, 2021

Re: K203722
Trade/Device Name: RayPilot System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: August 2, 2021
Received: August 2, 2021

Dear Hanna Syren:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K203722

Device Name
RayPilot® System

Indications for Use *(Describe)*
The RayPilot® System is intended for use as an adjunct in treatment planning and radiation therapy, to align and monitor the patient's position relative to the isocenter of a linear accelerator. The RayPilot® System provides accurate, precise, and continuous localization of a treatment isocenter by using RayPilot® HypoCath®, a transmitter located within one lumen of a urinary catheter, for prostate localization and tracking, and for automatic patient identification.

The device is limited for use to patients who both have prostate cancer and that would also be reasonably expected to require a urinary catheter for the duration of the radiation treatment, for example due to bladder outlet obstruction or patients who require a chronic indwelling Foley catheter.

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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## 510 (k) Summary of Safety & Effectiveness

This 510 (k) Summary of safety and effectiveness is provided in accordance with 21 CFR 807.92.

| | |
|---|---|
| Date of preparation: | August 25, 2021 |
| Submitter information: | Micropos Medical AB<br>Adolf Edelsvärds gata 11<br>SE – 414 51 Gothenburg<br>Sweden<br>Phone: +46 31 760 80 05 |
| Contact: | Hanna Syrén<br>Phone: +46 709 40 42 54 |
| Device trade name: | RayPilot® system |
| Common name | Patient Localization System |
| Classification name: | Accelerator, Linear, Medical |
| Classification: | 21 CFR 892.5050<br>Class II<br>Product code – IYE |
| Predicate device:<br>Reference Device: | Calypso 4D Localization system (K060906)<br>Silicone Foley Catheter 3-way (K063442) |

**Indications for use:**
The RayPilot® System is intended for use as an adjunct in treatment planning and radiation therapy, to align and monitor the patient's position relative to the isocenter of a linear accelerator. The RayPilot System provides accurate, precise, and continuous localization of a treatment isocenter by using RayPilot HypoCath, a transmitter located within one lumen of a urinary catheter, for prostate localization and tracking, and for automatic patient identification.

The device is limited for use to patients who both have prostate cancer and that would also be reasonably expected to require a urinary catheter for the duration of the radiation treatment, for example due to bladder outlet obstruction or patients who require a chronic indwelling Foley catheter.

**Device description:**
The RayPilot system is designed to provide accurate, objective and continuous localization of a treatment target for patient setup before treatment and target position monitoring during radiation therapy. The RayPilot system is an electromagnetic positioning system, which detects the transmitter in the RayPilot HypoCath, placed in the urethra, in the prostate. The RayPilot HypoCath is removed after finalized treatment.

The RayPilot system provides objective information about the location of the treatment target in real-time in 3 dimensions. The system operator uses the information to setup the patient for treatment and to monitor the position during radiation delivery.

**Predicate Comparison Table:**

| **FEATURE AND/OR SPECIFICATION OF DEVICE** | **Varian Medical Systems** Calypso 4D Localization System (K060906) | **Micropos Medical RayPilot System** |
|---|---|---|
| Intended use/ Indications for Use | The Calypso® 4D Localization System is intended for use as an adjunct in treatment planning and radiation therapy, to align and monitor the patient's position relative to the isocenter of a linear accelerator. The Calypso System provides accurate, precise, and continuous localization of a treatment isocenter by using two or more Beacon® transponders. Beacon transponders are indicated for permanent implantation in the prostate only. | The RayPilot® System with RayPilot® HypoCath® is intended for use as an adjunct in treatment planning and radiation therapy, to align and monitor the patient's position relative to the isocenter of a linear accelerator. The RayPilot System provides accurate, precise, and continuous localization of a treatment isocenter by using RayPilot HypoCath, a transmitter located within one lumen of a urinary catheter, for prostate localization and tracking, and for automatic patient identification.<br><br>The device is limited for use to patients who both have prostate cancer and that also require a urinary catheter, for example due to bladder outlet obstruction or patients who require a chronic indwelling Foley catheter. |
| Compatibility with radiation therapy environment | YES | YES |
| Compatibility with standard carbon fiber couch top | NO | YES |
| Used during patient set-up | YES | YES |
| Real-time target monitoring during treatment | YES | YES |
| Transmitter Technology | Nonionizing electromagnetic RF-localization of two or more (normally three) transponder beacons in relation to isocenter. | Nonionizing electromagnetic (EMF) RF-localization of one transmitter in relation to isocenter. |
| Receiver Technology | Relation to isocenter performed with a 4D electromagnetic array located between patient and gantry and suspended from a movable console on wheels | Relation to isocenter performed with a Receiver placed under the patient and on top of the treatment couch. |

| | | |
|---|---|---|
| Receiver placement | Receiver placed between patient and gantry | Receiver placed on the treatment couch, underneath the patient. |
| Ceiling mounted camera localization system required | YES | NO |
| Localization update frequency | 25 Hz | 30 Hz |
| Degrees of freedom (measurement) | 3D | 3D |
| Accuracy and precision in X, Y and Z respectively | Sub-mm | Sub-mm |
| Patient ID | NO | YES, automatic patient ID using transmitter ID |
| Preparations and invasiveness | Permanent surgical implantation of two or more Beacons before treatment | One non-permanent RayPilot HypoCath with a transmitter within a catheter is inserted in the urethra before treatment, and can be used for treatment planning without MR.<br>One non-permanent RayPilot ViewCath with a radio opaque marker is inserted in urethra at treatment planning and used solely for planning. |
| Permanent | YES, the Beacons are implanted permanently. | NO, the RayPilot HypoCath is removed at completion of radiation treatment. The RayPilot ViewCath is removed after treatment planning imaging. |
| Shelf life | 2 years for the Beacons, unknown for the Calypso detector | 3 years for the RayPilot HypoCath and RayPilot ViewCath, 5 years for the rest of the system. |
| Sterilisation Method | Gamma radiation | EtO |
| Patient size limitation | YES<br>Patient size limitation due to tracking depth cannot exceed 16 cm. | NO<br>Patient is lying on the Receiver, the tracking distance (from back to prostate) does not vary significantly with size. |
| Patient weight limitation | Patient with weight < 100 kg, BMI < 30 and waist/hip circumference < 100 cm are eligible | Patients with weight < 135 kg are eligible |
| MRI Safety after treatment | MR conditional | MR Safe |
| MR Safety during treatment | MR conditional | RayPilot HypoCath is MR Unsafe<br><br>RayPilot ViewCath is MR Safe |

**Performance testing:**
The RayPilot system have been the subject of performance testing, including design verification and validation, packaging, sterility, electromagnetic compatibility as well as other assessments to demonstrate that the system meets its intended use, is safe and effective and

performs comparably to legally marketed devices. Other types of testing, such as biocompatibility and software verification and validation are performed as well.

**Summary of non-clinical testing:**
Non-clinical testing demonstrates that the RayPilot system is safe and effective and performs comparably to legally marketed devices.

**Conclusion:**
The device is substantially equivalent to the predicate device listed above.