DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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July 25, 2017

Orfit Industries NV
% Mr. Dave Yungvirt
CEO
Third Party Review Group, LLC
The Old Station House
24 Lackawanna Place
MILLBURN NJ 07041

Re: K171734
Trade/Device Name: HP PRO Positioning Device
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: July 5, 2017
Received: July 7, 2017

Dear Mr. Yungvirt:

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,

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)*

K171734

Device Name

HP PRO Positioning Device

Indications for Use *(Describe)*

The HP PRO Positioning Device is indicated to assist in the proper positioning and repositioning of patients for radiation therapy and radiosurgery and treatment with protons.

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.

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date Prepared: June 27, 2017

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Device Information

Trade Name:	HP PRO Positioning Device
Model Number:	25000/19
Classification Name:	accelerator, linear, medical
Review Panel:	Radiology
Product Code:	IYE
Device Class:	Class II
Regulation:	892.5050

Predicate Device Information
K151207 Proton Immobilization Solution, Orfit Industries NV

Intended Use/Indications for Use
The HP PRO Positioning Device is indicated to assist in the proper positioning and repositioning of patients for radiation therapy and radiosurgery and treatment with protons.

Principle of Operation:
The HP PRO Positioning Device is used by first attaching it to the couch top utilizing the appropriate indexing. Then the health care provider positions the immobilization devices on to the HP PRO Positioning Device. Next the patient is helped onto the couch and positioned onto HP PRO Positioning Device in the appropriate immobilization device.

Conditions of Use:
The HP PRO Positioning Device is a patient positioning device intended to be used for the positioning and re-positioning of patients undergoing or receiving a course of external beam radiation therapy for the treatment of cancer and other diseases.

The HP PRO Positioning Device is intended to be used by or under the direction of a licensed physician. The HP PRO Positioning Device can be cleaned and disinfected by means of soapy water or an isopropanol based disinfectant, applied with a soft cloth.

Periodic checks of the HP PRO Positioning Device should be done to insure the parts are not worn and require repair or replacement

Models:

Model Name	Model Number
HP PRO Positioning Device	25000/19

Accessories:
There are no accessories marketed with the HP PRO Positioning Device. The HP PRO Positioning Device is made up of 4 components:

Quantity	Component Name	Component Material
1	Base Plate	PMMA and Carbon Fiber
1	Interface	Aluminum
4	Indexing Pins	POM (Polyoxymethylene)
8	Sheet Screws	Stainless Steel

Description:
The HP PRO Positioning Device is used by first attaching the base plate to the couch top utilizing the appropriate indexing. Then the health care provider positions the immobilization devices on to the HP PRO Positioning Device. Next the patient is helped onto the couch and positioned onto HP PRO Positioning Device in the appropriate immobilization device. An example of an immobilization device is the overlay base plate of the Proton Immobilization Solution.

The HP PRO Positioning Device is a device that assists in the proper positioning and repositioning of patients for radiation therapy and radiosurgery with protons. It is an accessory to the Proton Immobilization Solution. The HP PRO Positioning Device is typically attached to the treatment table and supports the patient during treatment. The proposed HP PRO Positioning Device is essentially an extension of the treatment table.

The Proton Immobilization Solution is a device which consists of a base plate which is attached to the treatment table. The patient lies on the base plate and a mask may be attached to the base plate so the patient is immobilized. The beam can pass through the mask and the base plate.

Proposed HP PRO Positioning Device is a device which is a rectangular piece of material onto which an immobilization device can be attached. This immobilization device can be a base plate for a mask. The patient lies on the base plate and a mask may be attached to the base plate so the patient is immobilized. The beam can pass through the mask and the base plate and through the HP PRO Positioning Device.

Dimensions

- Length – 50.17 inches
- Width – 21.61 inches
- Height – 1.62 inches

Weight

- 68.3 lbs.

Performance

Sag at cranial end – distributed weight 135kg:

Distributed weight	135 kg
Sag	9.21 mm

Creep at cranial end – distributed weight 135 kg:

Time	60 min.
Creep	0.214 mm

Dosimetric Properties:

The HP PRO Positioning Device has a uniform water equivalence thickness of 41.35mm. This means that the displacement of the maximum doses in the tissue towards the skin surface is 41.35mm.

Compatible devices and Thermoplastic Material:

The HP PRO Positioning Device is made from equivalent materials as the Proton Immobilization Solution.

SE Table of Attributes

Basic Unit Characteristics	Predicate K151207 Proton Immobilization Solution, Orfit Industries NV	K171734 HP PRO Positioning Device, Orfit Industries NV	Difference
Indications for Use	Indicated to assist in the proper positioning and repositioning of patients for radiation therapy and radiosurgery and treatment including electron, photon, and proton treatments.	Indicated to assist in the proper positioning and repositioning of patients for radiation therapy and radiosurgery and treatment with protons.	Removed treatment with electron, photon from indications since subject device is not intended to be used with these therapies.
Intended Use	Designed to be used for the positioning and repositioning of patients for receiving radiation therapy.	Designed to be used for the positioning and repositioning of patients for receiving radiation therapy.	None
Prescription	Rx	Rx	None
CFR	892.5050	892.5050	None
Materials of Construction	Base plate: Carbon fiber Indexing pins: Stainless steel	Base plate: PMMA and carbon fiber Interface plate: Aluminum Indexing pins: POM Sheet screws: Stainless steel	No new patient contacting materials added to subject device.
Fabrication	Machined and creation of sandwich structure with carbon fiber	Machined and creation of sandwich structure with carbon fiber	None
L x W x H	45-52” x 21” x 1.9”	50.17” x 21.61” x 1.62”	SE
water equivalence thickness	5.22mm	41.35mm	SE
Sag at cranial end	2.51mm (135kg distributed load)	9.21 mm (135kg distributed load)	SE
Creep at cranial end –at 60min.	0.0785mm (135kg distributed load)	0.214 mm (135kg distributed load)	SE

SE Table of Performance

Performance Category	SE Discussion
Patient Weight Distribution IEC60601-1	Patient lower part of legs not resting/supported by the proposed or predicate devices, both devices designed for Patients of up to 135 kg.
Tensile Safety factor IEC60601-1	Patients 135 kg. weight is to be reduced by 2 × 7.4% = 14.8% since the patient lower parts of legs are not supported in both devices. Tensile Safety Factor of 6.
Tensile Safety weight IEC60601-1	100% − 2 x (7.4%) = 85.2% leads to a total weight of 85.2% of the Patient weight, thus we get 135kg x 0.852= 115kg for both devices, all other tests are for 135kg. Device passes total load of 933.65kg. for 1 minute.
Elongation IEC60601-1	Elongation of break for both devices is less than 5%
Wear IEC60601-1	Neither the predicate or proposed system is impaired by wear
Mechanical Strength IEC60601-1	Both devices can handle a 150kg load to simulate the Patient (135kg) and the accessory (15kg). This weight was distributed around the Top Layer and carried the weight for minimum of 1 minute with no deformation or risks.
Mechanical Strength Sitting IEC60601-1	Both devices can handle a load of 60 % of the safe working load representing the patient or operator or a minimum 80 kg for one minute with the center of the load 60 mm from the outer edge of the support system. Device was tested with 90kg for 1 minute and passed.
Dynamic Forces IEC60601-1	Both devices can handle loads with a total mass of 153.3 kg. hanging a distance of 150 mm, and then dropped on the surface.
Flatness Test	Subject device has Flatness $\Delta < 1$ mm deviation
Surface Morphology	Subject device when visually inspected for polishing, milling, and absence of edge or surface damage or cavities meets specifications.
Sag	Sum of the sag and creep values (after 60minutes) is lower than 25mm. A 6DOF Robotic patient couch top can compensate the bending effect from patient weight.
Dimensions	Subject device has dimensions in thickness, length, and width all falling with specifications and tolerance of 0.1 – 0.2mm.
Creep	Sum of the sag and creep values (after 60minutes) is lower than 25mm. A 6DOF Robotic patient couch top can compensate the bending effect from patient weight.
Secondary radiation	Both proposed and predicate device experience SE values of secondary radiation when a patient plan using a typical spot scanning proton plan intended to deliver 1.8 Gy to a target volume of approximately 1 liter is simulated. Both have a half-life lower than 1 hour. Both have the same half-life of 20 minutes. No long- lived radio-isotopes are created by irradiating an acrylic couch top with a high energy proton beam.

Performance Category	SE Discussion
Spot Size	Both devices have SE lateral growth in spot size of a high-energy proton beam as it emerges. When a single spot of 228.8 MeV protons is directed through the devices the Gaf Chromic films are scanned and a two- dimensional Gaussian is fit to the exposed beam spots to determine the minor and major axis lengths of the elliptical beam spot and both spot sizes are the same 1.7-2.2mm both upstream and downstream.
WET and Distal Dose Falloff	Both devices perform SE when a monoenergetic proton beam of 228.8 MeV is directed into a Multi-Layer Ionization Chamber (MLIC). The charge is collected on each plane of the device and plotted against water equivalent depth to construct an integrated depth dose curve. The distal R80 (Depth of 80% dose) is recorded, as well as the distal falloff (distance between distal 90% and 20% dose levels). WET value of product that beam passes through is compensated for in treatment planning software, when it is considered too high.

SE Summary Statement

Difference in Indications for Use: Although we have removed treatment with electron or photon radiation therapies from the indications for use, no different questions of safety or effectiveness are raised when the subject device is used for its intended use (Proton Therapy). The subject device is substantially equivalent to the predicate device when used for its intended use (Proton Therapy).

Difference in Materials of Construction: Although we have added some materials to the subject device (PMMA, aluminum, and POM), no different questions of safety or effectiveness are raised when the subject device is used for its intended use because none of these materials have direct or indirect patient contact. The subject device is substantially equivalent to the predicate device when used for its intended use and according to its instructions for use.

SE Conclusion:
The HP PRO Positioning Device is substantially equivalent to K151207 Proton Immobilization Solution. Orfit is seeking FDA clearance for the HP PRO Positioning Device to market the subject device. There are no differences between the proposed and predicate devices other than minor differences explained in the SE Summary Statement. The proposed device is found to be SE to the predicate device.