DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 9, 2016

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

Re: K162862
Trade/Device Name: Raycast High Precision Lung Board Solution
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: October 13, 2016
Received: October 14, 2016

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 yours,

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)*

K162862

Device Name

Raycast High Precision Lung Board Solution

Indications for Use *(Describe)*

The Raycast High Precision Lung Board Solution 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. It is intended to be used by or under the direction of a licensed physician.

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

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: October 10, 2016

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Device Information

Trade Name:	Raycast High Precision Lung Board Solution
Model Number:	29115
Classification Name:	accelerator, linear, medical
Review Panel:	Radiology
Product Code:	IYE
Device Class:	Class II
Regulation:	892.5050

Predicate Device Information
K040773 Extended Butterfly Board, Bionix Development Corp.,

Intended Use/Indications for Use
The Raycast High Precision Lung Board 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. It is intended to be used by or under the direction of a licensed physician.

Principle of Operation
This product is a medical device used for positioning patients in radiation therapy. This system is used to position the arms over the head, for treating the thorax area.

Device Description
The Raycast High Precision Lung Board is used to position the patient supine on the treatment couch with the arms lifted above the head. This will keep the arms outside of the treatment field, which is the thorax in this case. The Raycast High Precision Lung Board is attached to the treatment couch with a 2-pin indexing bar in order to reproduce the same position each day. The Raycast High Precision Lung Board should be fully supported by the treatment couch. Then the patient is asked to lie down on the couch with his head in a head support that is attached to the Raycast High Precision Lung Board. Once the patient is lying down, he can lift up his arms until the elbows rest against the 'wings' of the board and the hands can reach the T-shaped handgrip.

The position of the T-shaped handgrip can be adjusted both in height and length according to the patient's anatomy. To adjust the height of the handgrip, pull the white knob on the side and move the grip pole up or down. To adjust the length of the handgrip, pull the white knob at the cranial side and slide the handgrip more caudally or cranially. Various head supports can be placed on the Raycast High Precision Lung Board depending on the physician's preference. The standard set-up will be with an Orfit Head Support, but it is also possible to use a Silverman or Timo Head Support which they might already have available in their department.

Once the patient is set-up correctly, the arms should not be blocking the treatment field anymore, which is the thorax area in this case. This allows the physician to irradiate the thorax from various angles, including laterally without passing through the arms of the patient. The Raycast High Precision Lung Board itself will not be in the treatment field and as such will not be irradiated through.

Accessories Description
There are no accessories marketed with the Raycast High Precision Lung Board.

Performance
No performance standards or special controls have been developed under Section 514 of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") for the Raycast High Precision Lung Board. Bench testing was performed and includes a dosimetry test report for the device including device attenuation and water thickness, which have been validated to demonstrate SE to the predicate in safety and effectiveness.

Additional studies performed are the MR safety studies performed in order to demonstrate that the device tested as MR safe.

Substantial Equivalence
Equivalence was determined using a side by side tabular comparison between the predicate and proposed devices which included: Features, Intended Use, Labeling, Materials, Specifications, Performance Data, and Technological Aspects. The proposed device is substantially equivalent to the K040773 Bionix Extended Butterfly Board.

SE Table of Attributes

Basic Unit Characteristics	**Predicate K040773 Bionix Development Corp., Extended Butterfly Board**	**Proposed Raycast High Precision Lung Board**	**Difference**
Indications for Use	To be used for the positioning and repositioning of patients undergoing or receiving a course of external beam radiation therapy for the treatment of cancer and other diseases. It is intended to be used by or under the direction of a licensed physician.	To be used for the positioning and repositioning of patients undergoing or receiving a course of external beam radiation therapy for the treatment of cancer and other diseases. It is intended to be used by or under the direction of a licensed physician.	None
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
Material Board Assembly	Acrylic	Acrylic	None
Material T Handle Base and Posts	POM + Nylon	POM + Nylon	None, to the best of our knowledge the predicate device accessories are made from the same POM and Nylon materials as the subject device. No different questions of safety or effectiveness are raised.
Material Flat Screws	Nylon	Nylon	None, to the best of our knowledge the predicate device accessories are made from the same POM and Nylon materials as the subject device. No different questions of safety or effectiveness are raised.
Material Socket Head Cap Screws and Knurled Thumbscrews	Nylon	None	Proposed device does not have these screws; SE is not affected since the proposed design does not require these screws to be SE. No different questions of safety or effectiveness are raised.

Basic Unit Characteristics	Predicate K040773 Bionix Development Corp., Extended Butterfly Board	Proposed Raycast High Precision Lung Board	Difference
Material Hand Grip Assembly	Vinyl	POM + Nylon	Both polymers are similar in grip characteristics. Both vinyl and nylon are SE materials for the hand grip, the primary difference between the materials is resistance to extreme temperatures, not applicable to this device. No different questions of safety or effectiveness are raised.
Material Attachment Pins	POM	POM	None, to the best of our knowledge the predicate device accessories are made from the same POM and Nylon materials as the subject device. No different questions of safety or effectiveness are raised.
Hand Grip Spring	None	Polyamide	Predicate device does not have this spring; SE is not affected since the predicate design does not require this spring to be SE. No different questions of safety or effectiveness are raised.
Fabrication	Machined and Thermoformed	Machined and Thermoformed	None
Design	Has elevated thermoformed "wings" on either side to support the patient's upper arms and facilitate patient positioning	Has elevated thermoformed "wings" on either side to support the patient's upper arms and facilitate patient positioning	None
Positioning	Handgrip included to help facilitate patient positioning and repositioning.	Handgrip included to help facilitate patient positioning and repositioning.	None
Mounting Holes	Yes	Yes	None
Thickness	0.31”	0.31”	None
L x W x H	22.4” x 21.3” x 6.7”	22.4” x 21.3” x 6.7”	None
Cleaning/ Disinfection in Labeling	To clean, wipe thoroughly with water based antiseptic cleaner or foam. Allow to dry before next patient use. Notice: Do not use alcohol based cleaners on this product	this product can be cleaned and disinfected by means of soapy water or an isopropanol based disinfectant, applied with a soft cloth	Minor difference in way of describing the cleaning/disinfection method, but the scope is the same, no difference in SE.

Basic Unit Characteristics	Predicate K040773 Bionix Development Corp., Extended Butterfly Board	Proposed Raycast High Precision Lung Board	Difference
Weight	6.24 lbs	6.24 lbs	None
MR Safety	Unknown	MR Safe	SE for attenuation, MR Safety, and skin build up was extrapolated based on the performance testing on the proposed device, and the SE comparison of material, fabrication method, thickness, and material density/thickness between the proposed and predicate device. The predicate device is made from similar non-magnetic material which contains a similar attenuation coefficient. It is fabricated using similar manufacturing methods to a similar thickness. The dimensions and weight are similar and the materials have similar density. The amount of attenuation and skin build up is directly related to the material properties, fabrication method, density, and thickness. Therefore, the predicate device contains similar inherent properties as the proposed device including attenuation and skin build up and MR safety.
Attenuation/SBU		~6MV (4.15%)	
Skin Build Up		~mmH2O/11mm	
Differences/Conclusion: There are no significant differences between the proposed and predicate devices, no new patient contacting materials are being introduced. Minor differences in the way labeling sections are described, some differences in the number of components included in the submission. The proposed device labeling is written to be more descriptive than the predicate labeling which does not introduce different questions of safety or effectiveness because the labeling is more clear. The proposed device contains less components compared to the predicate device, this does not introduce different questions of safety or effectiveness because the device functions equivalently to the predicate and introduces less materials and components to the patient. The proposed device is found to be SE to the predicate device.			