Orfit Industries NV
℅ Mr. Raymond Kelly
Consultant
Arazy Group Consultants, Inc.
3422 Leonardo Lane
NEW SMYRNA BEACH FL 32168

August 14, 2020

Re: K202068
Trade/Device Name: The AIO Solution 3.0
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: July 15, 2020
Received: July 27, 2020

Dear Mr. Kelly:

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)*

K202068

Device Name

The AIO Solution 3.0

Indications for Use *(Describe)*

The AIO Solution 3.0 is a positioning and immobilization system to set-up and reproduce the supine and prone position of belly & pelvic patients and the prone position of breast patients during radiation therapy.

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.

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Orfit Industries NV
9A Vosveld
2110 Wijnegem
Belgium

510(k) Summary
K202068

Date Prepared: August 12, 2020

I. SUBMITTER

Orfit Industries NV
9A Vosveld
2110 Wijnegem
Belgium

II. DEVICE

Name of Device: The AIO Solution 3.0, K202068
Common or Usual Name: Accelerator, linear, medical
Classification Name: Medical charged-particle radiation therapy system (21 CFR 892.5050)
Regulatory Class: II
Product Code: IYE

III. PREDICATE DEVICE

Name of Device: The AIO Solution, K191158.
This predicate has not been subject to a design-related recall.
Common or Usual Name: Accelerator, linear, medical
Classification Name: Medical charged-particle radiation therapy system (21 CFR 892.5050)
Regulatory Class: II
Product Code: IYE
Reference Device: Macromedics Pelvic Prone Board MR, K142420; CDR Systems Prone Breast Patient Positioning System, K122888

IV. DEVICE DESCRIPTION

The AIO Solution 3.0 with accessories provides the immobilization and positioning system necessary to set-up and reproduce the position of a patient for supine and prone belly & pelvic treatments or prone breast treatments in radiation therapy.

For belly & pelvic treatments, the AIO solution 3.0 base plates (already cleared; K191158) can be used in combination with the green AIO 3.0 belly & pelvic positioning cushions and accessories. Depending on the anatomy of the patient, 2 different sizes of belly inserts are available to make sure the intestines can be pulled out of the treatment area when in prone

position. The arms of the patient are positioned above the head to bring them out of the treatment field. A full belly insert should be used in supine position while the arms of the patient can be positioned on the chest to bring them out of the treatment field. The legs of the patient are supported by the grey AIO 3.0 knee & leg positioning cushions and/or the AIO 3.0 indexable feet support (already cleared; K191158). For increased precision, the set-up can be combined with an Orfit thermoplastic EFFICAST mask.

For prone breast treatments, the AIO solution 3.0 base plates (already cleared; K191158) can be used in combination with the yellow AIO 3.0 prone breast positioning cushions and accessories. The arms of the patient are positioned above the head to bring them out of the treatment field. The legs of the patient are supported by the grey AIO 3.0 knee & leg positioning cushions (already cleared; K191158). For increased precision, the set-up can be combined with an Orfit thermoplastic EFFICAST mask.

V. INDICATIONS FOR USE

The AIO Solution 3.0 is a positioning and immobilization system to set-up and reproduce the supine and prone position of belly & pelvic patients and the prone position of breast patients during radiation therapy.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Subject Device K202068 (The AIO Solution 3.0)	Predicate Device K191158 (The AIO Solution 3.0)
The AIO Solution 3.0 is a positioning and immobilization system to set-up and reproduce the supine and prone position of belly & pelvic patients and the prone position of breast patients during radiation therapy.	The AIO Breast and Lung Board Solution is a positioning and immobilization system to set-up and reproduce the supine position of a breast or lung patient during radiation. The AIO Head and Neck Solution is indicated to aid in supporting the knees or ankles of patients undergoing radiation therapy in the supine or prone position. The device is also used during image acquisition to support treatment planning.

Attributes	**Subject Device**	**Predicate Device K191158**	**Comparison**
Manufacturer	Orfit Industries NV	Orfit Industries NV	
Name	AIO Solution 3.0	AIO Solution	
Product Code	IYE	IYE	Same
Regulation	892.5050	892.5050	Same
Class	II	II	Same
Sterile	Non-Sterile	Non-Sterile	Same
Cleaned Before Use?	Yes	Yes	Same
Principle of Operation	Device uses AIO solution base plates cleared in K191158 for positioning and immobilization to set-up and reproduce the supine and prone position of patients during radiation therapy.	Device uses AIO solution base plates cleared in K191158 for positioning and immobilization to set-up and reproduce the supine and prone position of patients during radiation therapy.	Same
Device - Body Contact	Limited contact duration (<24 hours) surface contact (skin)	Limited contact duration (<24 hours) surface contact (skin)	Same
Sterility	Not sterile	Not sterile	Same
MR Safety	MR Safe	MR Safe (*Carbon fiber base plates = MR Unsafe*)	Both the predicate and subject devices are MR Safe, the carbon fiber plates in the predicate device are MR Unsafe. This does not raise different questions of safety and effectiveness because the subject device does not contain base plates.

Attributes	Subject Device	Predicate Device K191158	Comparison
Cleaning-Disinfection	Same	Same	The same cleaning procedures are intended to be used in the labeling, the predicate and subject materials are the same and the patient contact type with unbroken skin is the same for the same duration <24 hours.
Support Components	Contains leg separator components	Contains knee and ankle support components	Components are made from same materials
Cushion Materials	Polyethylene, Polyurethane, Polypropylene	Polyethylene, Polyurethane, Polypropylene	Same
Formed Materials	Polyethylene, Polyoxymethylene	Polyethylene, Polyoxymethylene	Same
Laminate Materials	Fiberglass	Fiberglass	Same
Packaging	PE bags, bubble wrap, PE foam, cardboard box	PE bags, bubble wrap, PE foam, cardboard box	Same

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

STERILIZATION:

Devices are non-sterile when used (and no processing required).

SHELF LIFE:

Device is made from durable inert polymers such as Polypropylene, Polyethylene, Polyurethane, and Polyoxymethylene which are provided nonsterile and have a low likelihood of time dependent product degradation, performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.

BIOCOMPATIBILITY:

Device has direct contact with intact skin, for a limited contact duration of ≤ 24 hours.
The patient contacting components of the AIO Solution 3.0 are constructed of the same Expanded Polypropylene, Polyethylene, Polyurethane, Glass Fiber Laminate, and Polyoxymethylene components which are cleared in the predicate AIO Solution (K191158) and the Expanded Polypropylene, Polyethylene, Polyurethane, Glass Fiber Laminate, and Polyoxymethylene materials that are used to construct the AIO Solution 3.0 are processed and manufactured in the same manner

as the Expanded Polypropylene, Polyethylene, Polyurethane, Glass Fiber Laminate, and Polyoxymethylene materials that are used to construct the predicate AIO Solution originally cleared in K191158. Biocompatibility testing is not needed because the materials, manufacturing, and processing in the AIO Solution 3.0 are identical to the predicate device. No new materials are being introduced in AIO Solution 3.0.

ELECTRICAL SAFETY AND ELECTROMAGNETIC COMPATIBILITY (EMC):
AIO Solution 3.0 does not contain active components.

SOFTWARE VERIFICATION AND VALIDATION:
AIO Solution 3.0 does not contain software or firmware.

CYBERSECURITY:
AIO Solution 3.0 does not contain ports or connections at risk for cybersecurity.

MRI SAFETY:
Expanded Polypropylene, Polyethylene, Polyurethane, Glass Fiber Laminate, and Polyoxymethylene were found to be non-magnetic and non-conductive. None of these materials pose a threat in the MR environment. The AIO Solution 3.0 are safe within an MR environment and pose no threat to patient safety. This analysis considers recommendations made by the FDA in its guidance published in December 2014 “Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment - Guidance for Industry and Food and Drug Administration Staff”.

PERFORMANCE TESTING:
Dosimetry testing was performed on the AIO Solution 3.0 to demonstrate substantial equivalence to the predicate device. Testing included measurement of attenuation and water equivalent thickness on different positions of the AIO Solution 3.0. Readings were taken at 6MV and 15MV. All measurements were scaled for output variations between calibration and measurement dates. The attenuation and the equivalent water thickness at predefined points of the material were defined. The measurements of the base plates show higher values for attenuation and water equivalent thickness on the places that were expected to have higher values: places where the plate has more carbon material or is reinforced.
The test data meets the A/R criteria predetermined for the device.

VIII. CONCLUSIONS

Through performance testing the subject device has demonstrated substantial equivalence to the predicate.