Qfix
% Alexandra Low Smythe
Senior Regulatory Affairs Specialist and Intellectual Property Specialist
440 Church Road
AVONDALE PA 19311

February 28, 2020

Re: K193243
Trade/Device Name: Alta™ Multipurpose Device
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE, LNH, JAI, JAK, LHN, KPS, OUO, FRZ
Dated: February 10, 2020
Received: February 11, 2020

Dear Alexandra Low Smythe:

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)*

K193243

Device Name
Alta™ Multipurpose Device

Indications for Use *(Describe)*

The Alta™ Multipurpose Device is intended to immobilize, support, position, and transfer patients undergoing radiotherapy procedures using electrons, photons, protons, including SBRT and SRS; imaging procedures such as x-ray, computed tomography, and magnetic resonance imaging; and other procedures involving transfer of a patient.

The Alta™ Multipurpose Device is designed to interface with the Symphony® Patient Transport System and other positioning devices, such as couch tops, thermoplastic masks, setup-specific treatment devices and adapters, and positioning supports and pads.

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

K193243

I. GENERAL INFORMATION

Establishment: WFR/Aquaplast Corporation/Anholt Technologies Inc., Dba Qfix
440 Church Road
Avondale, PA 19311 USA

Date Prepared: November 22, 2019

Manufacturer: Qfix
440 Church Road
Avondale, PA 19311 USA
Registration Number: 2247992

Contact Person: Alexandra Low Smythe
Senior Regulatory Affairs Specialist and Intellectual Property Specialist

Qfix
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Phone: 610 268-0585 Ext 736
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Device Name: Alta™ Multipurpose Device
Trade Name: Alta™ Multipurpose Device
Common Name: Multipurpose Positioning Solution and Accessories
Classification Name: Accelerator, Linear, Medical
Classification Panel: Radiology
Regulation Number: 21 CFR § 892.5050
Device Class: II
Product Code: Primary: IYE
Secondary: LNH, LHN, JAI, JAK, KPS, OUO, FRZ

II. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING SUBSTANTIAL EQUIVALENCE

Indications for Use

The Alta™ Multipurpose Device is intended to immobilize, support, position, and transfer patients undergoing radiotherapy procedures using electrons, photons, protons, including SBRT and SRS; imaging procedures such as x-ray, computed tomography, and magnetic resonance imaging; and other procedures involving transfer of a patient.

The Alta Multipurpose Device is designed to interface with the Symphony® Patient Transport System and other positioning devices, such as couch tops, thermoplastic masks, setup-specific treatment devices and adapters, and positioning supports and pads.

Device Description

Qfix has developed a new device designed to streamline radiotherapy and imaging workflows, the Alta™ Multipurpose Device. The Alta Multipurpose Device is intended to immobilize, support, position, and transfer patients undergoing radiotherapy procedures using electrons, photons, protons, including SBRT and SRS; imaging procedures such as x-ray, computed tomography, and magnetic resonance imaging; and other procedures involving transfer of a patient. The Alta Multipurpose Device is designed to interface with the Symphony® Patient Transport System and other positioning devices, such as couch tops, thermoplastic masks, setup-specific treatment devices and adapters, and positioning supports and pads.

The Alta Multipurpose Device is a versatile device, providing access for a variety of clinical setups for transport, imaging, and treatment on a single device. The proprietary fiber-reinforced composite construction of the Alta Multipurpose Device provides strong and rigid support while remaining lightweight for ease of transport and use. The Alta Multipurpose Device boasts broad-reaching compatibility with a variety of positioning and immobilization devices, including but not limited to:

- Headrests, adapters, and thermoplastics for head and neck applications, including intracranial, whole brain, and stereotactic radiosurgery (SRS),
- MR Coil Holders,
- Vacuum cushions for stereotactic body radiation therapy (SBRT),
- Bridges and compression devices for SBRT,
- Supine positioning devices for breast and thorax applications,
- Thoracic and pelvis thermoplastics for thorax and pelvis applications,
- Upper and lower extremity positioning devices, like hand grips, arm positioners, and knee and foot blocks.

When combined with such other devices through its variety of indexing features, the Alta Multipurpose Device enables a diverse set of clinical applications within the fields of radiotherapy and diagnostic imaging all with the same device, providing significant flexibility, agility, and efficiency for clinicians. Additionally, the Alta Multipurpose Device can optionally be configured to utilize Symphony Air Drive™ technology to facilitate patient transfers with the Symphony Patient Transport System, further enabling more efficient clinical workflows.

Predicate information

The subject device, the Alta™ Multipurpose Device, includes all of the device properties belonging to the predicate device, Patient Positioning Devices from MacroMedics, BV. The predicate device information follows:

Predicate Device Name	FDA Clearance Number and Date	Product code	Manufacturer
Patient Positioning Devices	K142420, cleared March 27, 2015	IYE	MacroMedics, BV

To date, this predicate device has not been subject to a design-related recall per information that is publicly accessible in the FDA recall database.

Comparison to Predicate Device

The Alta™ Multipurpose Device bears many similarities to its predicate, the MacroMedics Patient Positioning Devices. The Alta Multipurpose Device has the same fundamental Intended Use and purpose as the predicate device. Both the subject device and the predicate device are compatible with radiation therapy environments and diagnostic imaging environments. Both devices are non-sterile, reusable devices. Both devices are primarily constructed from fiber-reinforced composites. Both devices are appropriate for use in magnetic resonance environments, where indicated.

Performance Standards and Testing

The FDA has not established performance standards for this product under Section 514 of the Food, Drug and Cosmetic Act. Testing and analysis has been conducted to show that the verification, validation, and safety requirements have been met and are inclusive of the following considerations:

- Verification of hardware specifications
- Verification of MR safety characteristics
- Verification of compatibility with other devices
- Verification of attenuation characteristics
- Load rating
- Timed workflow studies
- Ease of use/ergonomic assessments

Non-clinical bench testing was conducted to support the intended use and to confirm that the proposed device is safe and effective and that technological changes do not raise any new issues of safety or effectiveness over the predicate device.

The Alta™ Multipurpose Device met all acceptance criteria for testing conducted and was appropriately validated to its intended use.

Safety and Effectiveness

Risk management is ensured via a risk analysis in compliance with ISO 14971:2007 to identify and provide reduction to potential hazards in a risk analysis beginning early in the design phase and continuing throughout the development of the product. These risks are controlled via measures realized in development, testing, and product labeling. To minimize risks, Qfix adheres to recognized and established industry practices and standards to minimize safety and performance risks. Furthermore, the operators and end users of the device are healthcare professionals familiar with and responsible for radiation therapy treatments, diagnostic imaging procedures, and other hospital procedures.

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device.

Substantial Equivalence

The subject device, the Alta™ Multipurpose Device, offers the following improvements over the predicate device, the MacroMedics Patient Positioning Devices (cleared under K142420 on March 27, 2015).

- **Subject device is radiolucent, low attenuating, and compatible with MR environments, all in one device**
- **Subject device accommodates MR imaging accessories such as coils and coil holders**
- **Subject device has improved ergonomics and usability features**
- **Subject device enables simplified and streamlined workflows**
- **Subject device is designed to accommodate Symphony® Air Drive™ technology to facilitate patient transfers with the Symphony Patient Transport System, further enabling more efficient clinical workflows**

However, the fundamental attributes of the subject device and the predicate device remain the same.

- **Both devices have the same fundamental intended use.**
  The Alta Multipurpose Device has the same fundamental intended use and overall general functionality as it relates to patient positioning, repositioning, and immobilization as the MacroMedics Patient Positioning Devices (cleared under K142420 on March 27, 2015).
- **Both the predicate and the subject device are intended to be used either independently or in conjunction with additional accessories, components, and standalone devices which are intended to immobilize, position and reposition patients undergoing radiation therapy and diagnostic imaging.**
  The predicate device is intended to be used in combination with other immobilization devices from MacroMedics. The Alta Multipurpose Device is intended to be used either independently or in conjunction with a number of existing positioning and immobilization devices via its indexing features,

creating a versatile, flexible solution for a diverse set of clinical applications in radiotherapy and diagnostic imaging.

- **Both devices may be used in MR environments.**
  Both the predicate device and subject device are intended for use in an MR environment where indicated. The predicate device provides for separate MR-compatible and non-MR compatible versions of its products, whereas the subject device is compatible with MR environments as well as x-ray, CT, and treatment environments on the same device.
- **Both devices are made of composite materials.**
  Both the predicate device and subject device are made of composite materials.

The conclusions from the non-clinical data suggest that the subject device has the same fundamental technological characteristics with respect to the predicate device and exhibits an equivalent safety and performance profile as that of the predicate device. Therefore, Qfix is of the opinion that the Alta Multipurpose Device does not raise new questions of safety or effectiveness and, therefore, is substantially equivalent to the marketed predicate device.