DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Qfix
Alexandra Low
Regulatory Affairs Specialist
Contact Address

July 11, 2017

Re: K171133
Trade/Device Name: Qfix® Abdominal/Thoracic Motion Control System, Qfix® SBRT Solution and Accessories
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE, LHN, JAI, OUO, JAK, KPS
Dated: June 16, 2017
Received: June 19, 2017

Dear Alexandra Low:

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,

For

Robert A. 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)*
K171133

Device Name
Qfix® Abdominal/Thoracic Motion Control System

Indications for Use *(Describe)*
Device-Specific Intended Use: The Qfix® Abdominal/Thoracic Motion Control System is intended to apply abdominal compression for managing internal body motion during respiration while maintaining maximum comfort to the patient. The Qfix® Abdominal/Thoracic Motion Control System is also intended to promote shallow breathing in radiation therapy or radiology.

System Intended Use: The Qfix® Abdominal/Thoracic Motion Control System can be used as part of the Qfix® SBRT Solution and Accessories including, Qfix's kVue™, Stradivarius™, VacQFix™ and DoseMax™ inserts, overlays, and standalone devices which are intended to immobilize, position and reposition patients undergoing radiation therapy including SBRT.

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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510K SUMMARY

I. GENERAL INFORMATION

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

Date Prepared: April 14, 2017

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

Contact Person: Alexandra Low
Regulatory Affairs Specialist

Qfix
440 Church Road
Avondale, PA 19311 USA
Phone: 610 268-0585 Ext 736
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Device Name: Qfix® Abdominal/Thoracic Motion Control System
Trade Name: Qfix® Abdominal/Thoracic Motion Control System, Qfix® SBRT Solution and Accessories
Common Name: SBRT Positioning Solution and Accessories; Abdominal/Thoracic Motion Control System; Compression Belt
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

II. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING SUBSTANTIAL EQUIVALENCE

Indications for Use

Device-Specific Intended Use: The Qfix® Abdominal/Thoracic Motion Control System is intended to apply abdominal compression for managing internal body motion during respiration while maintaining maximum comfort to the patient. The Qfix®

Abdominal/Thoracic Motion Control System is also intended to promote shallow breathing in radiation therapy and radiology.

System Intended Use: The Qfix® Abdominal/Thoracic Motion Control System can be used as part of the Qfix® SBRT Solution and Accessories including, Qfix's kVue, Stradivarius, VacQFix and DoseMax inserts, overlays, and standalone devices which are intended to immobilize, position and reposition patients undergoing radiation therapy including SBRT.

Device Description

Qfix has developed an improved device, the Qfix® Abdominal/Thoracic Motion Control System, to promote shallow breathing in patients undergoing radiation therapy including electron, photon, and proton treatments and general radiology and imaging applications including MR and CT image acquisition. The Qfix® Abdominal/Thoracic Motion Control System is intended to be used either independently or in conjunction with a number of existing devices and accessories in the Qfix portfolio to create a comprehensive solution for stereotactic body radiation therapy.

The Qfix® Abdominal/Thoracic Motion Control System features belts and paddles of varying size, an air bladder, and a hand pump with gauge. The belts come in multiple sizes to accommodate wide range of patient girths. The rigid foam paddles are designed with geometry that conforms to the region beneath the xiphoid process, in order to provide relatively comfortable compression that does not compress the ribs themselves. The paddles also feature embedded fiducial markers, providing another means of positional localization.

Compression is achieved via a bladder attached to the paddles, designed to maintain a flat profile even when fully inflated in order to achieve uniform pressure on the paddle through the course of the procedure. The bladder, which is inflated with a detachable small hand pump with gauge, features a pressure-holding valve and a quick release at the junction of the pump and the inflation tubing. This allows the Abdominal/Thoracic Motion Control System to reliably hold its pressure without the pump in place, enabling more flexibility and versatility in studies and procedures. At the time of this submission, the Qfix® Abdominal/Thoracic Motion Control System is patent pending.

The Qfix® Abdominal/Thoracic Motion Control System can be used in conjunction with other devices already in the Qfix Product Portfolio to achieve further body immobilization or greater degrees of compression with the Qfix® SBRT Solution and Accessories. It combines a rigid, low attenuating support structure in the form of a couchtop insert or overlay with a series of interchangeable devices such as supportive cushions, compression devices, and other immobilization devices, including the Qfix® Abdominal/Thoracic Motion Control System, allowing clinicians to provide superior immobilization customized to the unique treatment plan of each patient.

Predicate information

The subject device, the Qfix® Abdominal/Thoracic Motion Control System, includes all of the device properties belonging to the predicate device, the Body Pro-Lok™ Respiratory Plate with Cushion, Body Pro-Lok™ Respiratory Belt from MEDTEC, Inc. (CIVCO Medical Solutions). The predicate device information follows:

Predicate Device Name	FDA Clearance Number and Date	Product code	Manufacturer
Body Pro-Lok™ Respiratory Plate with Cushion, Body Pro-Lok™ Respiratory Belt	K153026, cleared May 25, 2016	IYE	MEDTEC, Inc. d/b/a CIVCO Medical Solutions

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

Comparison to Predicate Device

The Qfix® Abdominal/Thoracic Motion Control System bears many similarities to its predicate, the MEDTEC/CIVCO Body Pro-Lok devices. The Qfix® Abdominal/Thoracic Motion Control System has the same Intended Use and purpose as the predicate device. Both the subject device and the predicate device are compatible with radiation therapy environments, including but not limited to external beam therapy, photon therapy, and proton therapy. Both devices are non-sterile, reusable devices manufactured from non-magnetic materials with the exception of the hand pump/pressure gauge. Both devices have been validated for use in magnetic resonance environments.

The subject device offers the following improvements over the predicate.

- **The device is intended to be used independently or in conjunction with other devices, allowing for improved setup flexibility for a variety of clinical applications.**
- **Produces MR Images without artifacts.**
- **Improved positional accuracy and consistency provided by embedded fiducial markers.**
- **Novel geometry contributes to additional ability to localize patient anatomy.**
- **Provides improved pressure retention.**
- **Additional considerations for patient comfort, including paddle geometry designed to conform to patient anatomy.**

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.

Non-clinical bench testing, customer preference validation, as well as a literature review was conducted to support the intended use.
A literature review was conducted to support the intended use. The literature demonstrates that devices such as the Qfix® Abdominal/Thoracic Motion Control System and the MEDTEC/CIVCO Body Pro-Lok devices are widely, safely, and effectively used in applying abdominal compression for managing motion of internal structures, such as organs and tumors.

Non-clinical testing was completed to confirm that the proposed device is safe and effective and to confirm that technological changes do not raise any new issues of safety or effectiveness over the predicate. The Qfix® Abdominal/Thoracic Motion Control System was tested for MR Safety and compatibility using methodologies presented in ASTM F2119-07 and F2052-15.

The Qfix® Abdominal/Thoracic Motion Control System passed acceptance criteria for magnetically induced displacement force and was demonstrated conditionally for use in MR field strengths up to and including 3T. The Qfix® Abdominal/Thoracic Motion Control System did not artifact or produce image artifacts when imaged in a 3T MRI scanner.

Performance characteristics pertaining to shallow breathing for the Qfix® Abdominal/Thoracic Motion Control System were also tested by comparing tidal volume and inspiratory capacity in healthy volunteers with and without Abdominal/Thoracic Motion Control System application.

Healthy volunteers exhibited a statistically significant reduction in inspiratory capacity and tidal volume while wearing the pressurized Qfix® Abdominal/Thoracic Motion Control System, which correlates to a decrease in motion of the diaphragm, and therefore shallow breathing.

The Qfix® Abdominal/Thoracic Motion Control System met all acceptance criteria for testing conducted and was validated per its intended use.

Safety and Effectiveness

Risk management is ensured via a risk analysis in compliance with ISO 14971:2007 to identify and provide mitigation 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 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, with improved localization, greater patient comfort and compliance, enhanced MR Compatibility and non-artifacting status, and the expanded ability to be used with a wider selection of treatment, simulation, and imaging modalities, possesses a unique ergonomic advantage in catering to the specific needs of each individual patient. However, the fundamental attributes of the subject device and the predicate device are the same.

- Both devices have the same intended use.
  The Qfix® Abdominal/Thoracic Motion Control System has the same intended use and overall general functionality as it relates to patient positioning, repositioning, and immobilization as the Body Pro-Lok™ Respiratory Plate with Cushion, Body Pro-Lok™ Respiratory Belt (K153026, cleared May 25, 2016).
- Even though the subject device may be used independently, both the predicate and the subject device are intended to be used together with additional accessories inserts, overlays, and standalone devices which are intended to immobilize, position and reposition patients undergoing radiation therapy including SBRT.
  The Body Pro-Lok devices are intended to be used in combination with CIVCO Medical Solutions Body Pro-Lok System for SBRT. The Qfix® Abdominal/Thoracic Motion Control System is intended to be used System is intended to be used either independently or in conjunction with a number of existing devices and accessories in the Qfix portfolio to create a comprehensive solution for stereotactic body radiation therapy.

- Both devices may be used in MR environments.
  Both the Body Pro-Lok devices and the Qfix® Abdominal/Thoracic Motion Control System are made with non-magnetic materials where possible, and any limitations are indicated in the Instructions for Use. Testing was conducted on both devices using methodologies presented in ASTM F2119-07 and F2052-14 and both devices passed testing.

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 Qfix® Abdominal/Thoracic Motion Control System does not raise new questions of safety or effectiveness and, therefore, is substantially equivalent to the marketed predicate device.