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

June 14, 2016

Qfix
% Ms. Nadia Sookdeo Harhen
Regulatory Affairs Manager
440 Church Road
AVONDALE PA 19311

Re: K160627
Trade/Device Name: Symphony™ Patient Transport System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE, LNH, FRZ, LHN, JAI, JAK, KPS, OUO
Dated: May 20, 2016
Received: May 23, 2016

Dear Ms. Harhen:

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)*

K160627

Device Name
Symphony™ Patient Transport System

Indications for Use *(Describe)*

The Qfix® Symphony Patient Transport System is indicated to aid in the support, positioning, and transfer of a patient for procedures involving imaging, including MRI; and external beam radiation therapy treatment with electrons, photons or protons; and other procedures requiring transfer of a patient. The Symphony is designed to interface with other positioning devices, such as couchtops, inserts, thermoplastic masks, and positioning 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Device Act 1990 and 21 CFR § 807.92.

I. General Information

Establishment

Anholt Technologies, Inc. DBA Qfix
440 Church Road
Avondale, PA 19311 USA

Date Prepared

March 4, 2016

Manufacturer

Qfix
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Avondale, PA 19311 USA
Registration Number: 2247992

Contact Person

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Regulatory Affairs Manager

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Avondale, PA 19311 USA
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Device Name

Symphony™ Patient Transport System

Trade name:	Symphony™ Patient Transport System
Common Name:	Powered Patient Transfer Device
Classification Name:	Medical charged-particle radiation therapy system
Classification Panel:	Radiology
Regulation number:	21 CFR § 892.5050
Device Class:	II
Product Code:	Primary: IYE, Secondary: LNH, FRZ, LHN, JAI, JAK, KPS, OUO

II. Safety and Effectiveness Information Supporting Substantial Equivalence

Indications for Use

The Qfix® Symphony™ Patient Transport System is indicated to aid in the support, positioning, and transfer of a patient for procedures involving imaging, including MRI; and external beam radiation therapy treatment with electrons, photons or protons; and other procedures requiring transfer of a patient. The Symphony, is designed to interface with other positioning devices, such as couchtops, inserts, thermoplastic masks and positioning pads.

Device Description

Qfix, has developed the Symphony™ Patient Transport System to seamlessly move patients among multiple imaging modalities such as MR and CT to treatment modalities, such as those utilizing photon or proton and other procedures requiring the transfer of a patient. The Symphony™ Patient Transport System is designed to utilize a low-friction air bearing to transfer patients from one surface to another, eliminating the need to manually lift the patient. Additionally, the design enables clinicians to set up a patient on the Symphony™ for subsequent transfer and immobilization throughput in cancer treatments and other procedures. Qfix intends to market the Symphony™ Patient Transport System which consists of the Symphony™ trolley and several transfer surfaces including; a standard transfer surface, a head/neck transfer surface, and a brachytherapy solution which are compatible with existing patient positioning devices. The Symphony™ Patient Transport System is designed to optimize workflow efficiencies and improve patient outcomes.

Performance Standards and Testing

The FDA under Section 514 of the Food, Drug and Cosmetic Act has not established performance standards for this product, however testing and analysis has been conducted to show that the verification, validation and safety requirements have been met. Performance, safety, labeling, usability, software and mechanical requirements were all part of verification and validation for the Symphony™ Patient Transport System. This analysis includes:

- Verification of hardware specifications, power requirements and control functions per IEC 60601-1 Ed. 3
- Verification of transfer method
- Verification of usability of components, e.g. side rails, emergency stop, memory sets
- Life cycle testing and analysis of expected life of components, e.g. side rails, pillars, batteries, blower, power, emergency stop, etc, per intended use
- Load rating, deflection requirements, protection against electrical hazards, protection against mechanical hazards, construction of the equipment, durability electromagnetic compatibility per IEC 60601-1 Ed. 3
- Verification of aluminum equivalence/attenuation

- Verification of MRI Safety of transfer surfaces and the Symphony™ trolley by performing magnetic attraction tests with MRI scanners at 0.35T, 1.5T, and 3T.
- Validation of user interface, ease of use/ergonomics through clinical user assessments

No clinical or animal studies were completed to support the subject device and the substantial equivalence argument however, analysis of electronic and mechanical components, and verification of MRI compatibility as well as radiographic properties were conducted to support the efficacy and safety features the Symphony™ Patient Transport System. Radiographic measurements indicated that the transfer surfaces were radiolucent and were low attenuating relative to other radiotherapy positioning devices currently on the market with Aluminum Equivalence measuring less than 0.55mm/mm. Force of magnetic attraction tests as well as electronic functionality tests were conducted and the Symphony™ trolley proved to be MR Conditional to 3T, allowing for lateral transfers of patients adjacent to the bore of the MRI machine. The Symphony™ transfer surfaces proved to be MR Safe. The results from usability studies showed that the Symphony was intuitive, easy to use and promoted workflow efficiency and patient throughput.

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, such as IEC 60601-1, 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.

Predicate information

The subject device, Symphony™ Patient Transport System, includes all of the device properties belonging to the predicate device, the Zepher Patient Positioning and Transfer System. The predicate device information follows:

Predicate Device Name	***FDA Clearance Number and Date***	***Product code***	***Manufacturer***
Diacor Zephyr "x-series" Patient Positioning and Transfer System	K121929, cleared January 17, 2013	LHN	Diacor Inc.

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.

There is no reference device for this premarket notification.

Comparison to Predicate Device

The subject device, Symphony™ Patient Transport System, has the same Intended Use as the predicate device and uses a similar low friction, air technology as the predicate device in order to complete patient transfers. Both the subject device and the predicate device are compatible with MR and radiotherapy environments and devices are designed for use in other types of procedures that require the transfer of a patient. The transfer surface of the Symphony™ and the baseboard of the Zepher function as an accessory to support and position patients using positioning aids.

The subject device, Symphony™ Patient Transport System, offers the following new and improved features with respect to the predicate device, Diacor Zephyr "x-series" Patient Positioning and Transfer System (cleared with K121929 on January 17, 2013).

- **Improved** air blower is integrated into the system, rather than through the use of an external accessory air blower
- **MRI Safety** has been improved, with the Symphony™ trolley and transfer handles being MR Conditional and the transfer surfaces being MR Safe
- **Improved** Ergonomics and usability
- **Improved** patient safety with side rails integrated on the Symphony™ trolley and ability to index to the receiving modality
- **Improved** clinician safety with transfer handles which aid in patient transfers
- **Increased** convenience through the inclusion of memory presets for devices commonly used for transfers
- **Increased** flexibility of user operation for loading and unloading patients with easily adjustible pillars
- **Improved** power consumption requirements, allowing for battery operation

Substantial Equivalence

The Symphony™ Patient Transport System has the same intended use and overall general functionality as it relates to aiding, supporting, positioning and transferring patients as the Diacor Zephyr "x-series" Patient Positioning and Transfer System (cleared with K121929 on January 17, 2013).

The differentiating features of the subject device demonstrate that the Symphony™ Patient Transport System is a robust device that can be used for conducting patient transfers in various settings in the clinical environment. Improvements made to the user interface supports workflow efficiency and safety of patients and staff alike. While the improved MR compatibility features and the adjustability of the Symphony™ Patient Transport System allow for more flexibility in use, the fundamental attributes of the subject device and the predicate device are the same.

The conclusions from the non-clinical data suggest that the features have 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 Symphony™ Patient Transport System does not raise new questions of safety or effectiveness and is substantially equivalent to the currently marketed Diacor Zephyr "x-series" Patient Positioning and Transfer System (K121929).