Qfix
% Mckenzie Banasik
Sr. Regulatory Affairs Specialist
440 Church Road
AVONDALE PA 19311

March 31, 2023

Re: K230312
Trade/Device Name: Iris AirShuttle™
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE
Dated: February 1, 2023
Received: February 3, 2023

Dear Mckenzie Banasik:

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,

Lora D. Weidner -S

Digitally signed by Lora D. Weidner -S
Date: 2023.03.31 14:41:22 -04'00'

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: Division of Radiological Imaging and Radiation Therapy Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230312

Device Name
Iris AirShuttle™

Indications for Use *(Describe)*
Device-Specific Indications for Use/Intended Use: This device is intended for use as part of the AirDrive system to facilitate diagnostic and image guided procedures including under fluoroscopy, X-ray, CT, MR, other imaging procedures, and other procedures involving transfer of a patient.

System Indications for Use/Intended 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.

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.

510(K) SUMMARY

A. **Submitter Information**

Submitter Name & Address:	Qfix 440 Church Road Avondale, PA 19311, USA
Contact Person:	McKenzie Banasik, Sr. Regulatory Affairs Specialist Telephone: 319-248-6544 Primary E-mail: mckenzie.banasik@civcort.com Secondary E-mail: regulatory@qfix.com
Date Summary Prepared:	February 1, 2023
Trade Names:	Symphony® Patient Transport System, Iris™, Iris AirShuttle™
Common Names:	Patient Transfer Device
Classification Names & Numbers	Medical charged-particle radiation therapy system (892.5050)
Device Class:	Class II
Review Panels:	Radiology
Product Codes:	Primary: IYE Secondary: LNH, FRZ, LHN, JAI, JAK, KPS, OUO, IZI, OWB

B. **Safety and Effectiveness Information Supporting Substantial Equivalence**

Indications for Use/Intended Use Statements

Device-Specific Indications for Use/Intended Use: This device is intended for use as part of the AirDrive system to facilitate diagnostic and image guided procedures including under fluoroscopy, X-ray, CT, MR, other imaging procedures, and other procedures involving transfer of a patient.

System Indications for Use/Intended 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 made a modification to its previously cleared Symphony Patient Transport System (cleared in K160627). This modification introduces a new transfer device variant compatible with the Symphony Patient Transport System – the Iris AirShuttle. The Iris AirShuttle is designed to be used with an AirDrive source, such as the AirDrive Trolley or AirDrive Caddie, to provide a solution for a complete patient transport system. With the Iris AirShuttle, the system is capable of being used in multimodal imaging and treatment environments, including interventional radiology procedures and workflows involving fluoroscopy, angiography, and magnetic resonance imaging. To facilitate these workflows, user configurable accessory rails have been added to the design, allowing easy transfer of essential rail-mounted equipment with the patient. Additionally, the Iris AirShuttle allows for patient transfer on soft and hard surfaces. Device pads have been included in the modification to maximize patient comfort while minimizing the distance between the patient and the spine coil of MR machines for optimal image quality. Alternative integrated transfer handles have also been included to allow for transfers with or without air power and without installation of the removable transfer handles. Qfix intends to market the subject device for use with the AirDrive Trolley and the AirDrive Caddie. This creates an improved efficient workflow while reducing the risk of injuries related to manually lifting patients for transport in various treatment environments, including multimodal imaging and treatment workflows involving fluoroscopy, angiography, and magnetic resonance imaging.

Predicate Device

The proposed modification to the Symphony Patient Transport System, including the Iris AirShuttle, is substantially equivalent and includes all the device properties belonging to the following predicate device:

Predicate Device Name	FDA Clearance Number and Date	Product Code	Manufacturer
Symphony™ Patient Transport System	K160627, cleared June 14, 2016	IYE	Qfix

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 of Predicate Device

The proposed Iris AirShuttle includes many of the same features as the predicate device, Symphony Patient Transport System. Both the predicate and subject device are compatible with multimodal imaging and treatment environments, including CT, MR, X-ray, other imaging procedures and other procedures involving transfer of a patient. Both devices are non-sterile, reusable devices manufactured from the same fiber-reinforced composite materials.

Additionally, the subject device can be used in fluoroscopy and angiography environments, including multimodal workflows including magnetic resonance imaging. User configurable accessory rails have been added for ease of transfer of essential rail mounted equipment with the patient and device pads

have been included to maximize patient comfort while minimizing the distance between the patient and the spine coil of MR machines for optimal image quality. Alternative integrated transfer handles have been included in this modification to allow for transfers with or without air power and without installation of the removable transfer handles.

Performance Standards and Testing

The FDA has not established performance standards for this product under Section 514 of the Food, Drug and Cosmetic Act; however, bench testing and analysis has been conducted to show that the verification, validation and safety requirements have been met for the subject device when used as part of the Symphony Patient Transport System.

- Verification of transfer method
- Verification of usability of components, e.g configurable side accessory rails, pads, alternative integrated transfer handle
- Verification of MRI Safety of transfer surfaces by performing magnetic attraction tests with MRI scanners at 3.0T
- Life cycle testing and analysis of expected life of components, e.g configurable side accessory rails, pads, alternative integrated transfer handle
- Load rating
- Validation of ease of use/ergonomics
- Fluoroscopy verification and validation testing using angiography table
- Verification of aluminum equivalence/attenuation

No clinical or animal studies were completed to support the subject device and substantial equivalence argument; however, analysis of mechanical components and verification of MRI compatibility as well as radiographic properties were conducted to support the efficacy and safety features of the Iris AirShuttle. Radiographic measurements indicated the device is radiolucent and low attenuating in the imaging region. Testing in an MR environment was conducted, and the Iris AirShuttle was shown to be MR Conditional up to 3T magnetic field strength. The results from usability studies showed the Iris AirShuttle was intuitive, easy to use, and promoted workflow efficiency.

Safety and Effectiveness

Risk management was conducted via a risk analysis in compliance with ISO 14971:2019 to identify and provide mitigation to potential hazards early in the design process and continuing through product development. The risks are controlled via risk-reduction measures assessed in design, development, testing and product labeling. Qfix adheres to recognized and established industry standards and practices to minimize risk associated with performance and safety. Additionally, the intended users of the subject device are healthcare professionals responsible and familiar with typical procedures involving diagnostic imaging and treatment.

The subject device's labeling contains instructions for use and any necessary precautions and warnings to provide effective and safe use of the device.

Substantial Equivalence

The subject device, Iris AirShuttle, offers the following similarities to the predicate device, the Symphony Patient Transport System (cleared under K160627, on June 14, 2016).

- **The same fundamental intended use**
  Device-Specific Indications for Use/Intended Use: This device is intended for use as part of the AirDrive system to facilitate diagnostic and image guided procedures including under fluoroscopy, X-ray, CT, MR, other imaging procedures, and other procedures involving transfer of a patient.

  System Indications for Use/Intended 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.

  The subject device is intended to be used with compatible AirDrive air sources providing a solution for a complete patient transport system in various treatment and imaging modalities, including interventional radiology procedures and workflows involving fluoroscopy, angiography, and magnetic resonance imaging. Therefore, the subject device has the same fundamental intended use as the predicate device when used with compatible devices.

- **Both devices provide a patient transfer method for treatment environments, imaging procedures, and other procedures involving patient transfer.**

  The Iris AirShuttle, when used with AirDrive sources, such as the AirDrive Trolley or AirDrive Caddie, provides the same patient transfer capabilities as the Symphony Patient Transport System.

- **Both devices may be used in MR environments.**
  Both predicate and subject devices have been tested for MR compatibility and are capable of being used in MR environments. This testing concludes that the subject and predicate device are MR conditional up to 3T magnetic field strength as defined by ASTMF2503-20 section 3.1.11.

- **Both devices have similar technical characteristics.**
  The subject device, Iris AirShuttle, is composed of the same fiber-reinforced composite material as the transfer devices of the predicate device, Symphony ™ Patient Transport System. Both devices have similar design features including length, width, and load rating (500 lbs). Both subject and predicate are non-sterile, reusable devices.

As supported by the non-clinical data and design control activities, 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 asserts that the Iris AirShuttle does not raise new questions of safety and effectiveness; therefore, the subject device is substantially equivalent to the marketed predicate device.