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

December 4, 2015

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

Re: K152321
Trade/Device Name: Encompass™ SRS Immobilization System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: November 30, 2015
Received: December 1, 2015

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)*
K152321

Device Name
Encompass™ SRS Immobilization System

Indications for Use *(Describe)*
The Encompass™ SRS Immobilization System provides noninvasive stereotactic head and neck immobilization by using a patient specific thermoplastic mask that conforms to the patient's features to provide accurate, reproducible positioning, repositioning and immobilization. The Encompass™ SRS Immobilization System allows the patient to undergo diagnostic imaging in the same position as that of the treatment position enabling more accurate 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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 August 14, 2015

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

Contact Person Mrs. Nadia Harhen
Regulatory Affairs Manager

Qfix
440 Church Road
Avondale, PA 19311 USA
Phone: (610) 268-0585
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Device Name Encompass™ SRS Immobilization System

Common Names: Thermoplastic (moldable), patient positioning device
Classification Name: Medical charged-particle radiation therapy system
Classification Panel: Radiology
CFR Code: 21 CFR § 892.5050
Classification: Class II
Product Code: Primary: IYE, Secondary: LHN, JAI, JAK, LNH, KPS, OUO

II. Safety and Effectiveness Information Supporting Substantial Equivalence

Indications for Use

The Encompass™ SRS Immobilization System provides noninvasive stereotactic head and neck immobilization by using a patient specific thermoplastic mask that conforms to the patient's features to provide accurate, reproducible positioning, repositioning and immobilization. The Encompass™ SRS Immobilization System allows the patient to undergo diagnostic imaging in the same position as that of treatment, enabling radiation therapy.

Device Description

The Encompass™ SRS Immobilization System is a highly advanced, non-invasive immobilization solution designed for precisely targeted brain, head and neck treatments. The Encompass™ SRS Immobilization System consists of a posterior support of either a Fibreplast™ thermoplastic mask, or a Moldcare cushion which rests on a contoured surface. The Encompass™ SRS Immobilization System features the IntegraBite™, which reduces motion allowing for maximum dose to the tumor while minimizing radiation delivered to the surrounding healthy tissue. The Integrated Shim System™ enables quick and seamless 0.5 mm height adjustments of the thermoplastic mask for a fully customizable patient setup. The Encompass™ SRS Immobilization 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, usage, and consumable requirements were all part of verification and validation for the Encompass™ SRS Immobilization System. This analysis includes:

- Verification of hardware specifications
- Timed workflow studies
- Ease of use/ergonomics assessments
- Load rating per IEC 60601-1 Ed. 3
- Verification of aluminum equivalence
- Verification of deflection requirements per IEC 60976
- Verification of MRI Safety, compatibility with optical tracking systems

No clinical studies were completed to support the subject device and the substantial equivalence argument however, analysis of positioning accuracy and immobilization studies were conducted to support the efficacy and safety features the Encompass™ SRS Immobilization System offers. Motion studies were conducted on healthy volunteers by tracking forced and resting motion with the Encompass mask for 15 minutes. It was concluded that the subject device with and without Integrabite™ provides submillimeter stability under resting conditions. Intrafactionation studies were also conducted at a clinical site, which established that the intrafractionation motion was less than 1mm/1°. Workflow studies. It was concluded that masks could be formed in under 5 minutes with a total touch time during the mask making workflow of 20 minutes or less.

Safety and Effectiveness

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

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 the treatment of radiation therapy.

Predicate information

The subject device, Encompass™ SRS Immobilization System, includes all of the device properties belonging to the predicate device, the AccuFix Radiolucent Patient Immobilization System. The predicate device information follows:

Predicate Device Name	***FDA Clearance Number and Date***	***Product code***	***Manufacturer***
AccuFix Radiolucent Patient Immobilization System	K032156, cleared September 2, 2003	IYE	WFR/AQUAPLAST CORP (Qfix)

This predicate has not been subject to a design-related recall.
There is no reference device for this premarket notification.

Comparison to Predicate Device

The subject device, Encompass™ SRS Immobilization System, offers the following new features with respect to the predicate device, AccuFix Radiolucent Patient Immobilization System (Cleared with K032156, September 2, 2003).

- **New** Shimming which is integrated into the system
- **Improved** Ergonomics
- **Improved** Immobilization
- **New** optional IntegraBite™
- Utilizes variable perf Fibreplast Thermoplastic, with new coating (predicate device utilizes both Aquaplast and Fibreplast Thermoplastics). Note that the mask can be open or closed view.

Substantial Equivalence

The predicate device, AccuFix Radiolucent Patient Immobilization System is designed to be used with Aquaplast™ or Fibreplast™ Thermoplastic (K935067) masks to immobilize, position and reposition patients undergoing radiation therapy utilizing a linear accelerator treatment table. The AccuFix Immobilization Board attaches or mounts to a treatment table or to a Qfix Radiolucent Replacement Couchtop, which in turn mounts to the treatment table with a specific focus on the head/neck. This system was modified to expand the portfolio offering to the Encompass™ SRS Immobilization System which has a specific focus on superior immobilization and integrated patient shimming as it pertains to the head/neck regions.

The subject device is the Encompass™ SRS Immobilization System, consists of a rigid support device and a thermoplastic consumable, where the device can either be one of three options: a kVue insert, an Encompass™ standalone device or an MRI version of the Encompass™ device.

The superior immobilization and integrated patient shimming attributes of the Encompass™ SRS Immobilization System give the subject device greater capabilities than the predicate device, especially as it pertains user ergonomics and immobilization. However, the Encompass™ SRS Immobilization System is an extension of the functionalities of the predicate.

The conclusions from the non-clinical data suggest that the features are of similar technological characteristics with respect to the predicate device and bear an equivalent safety and performance profile as that of the predicate device

Therefore, Qfix is of the opinion that Encompass™ SRS Immobilization System does not raise new questions of safety or effectiveness and is substantially equivalent to the currently marketed AccuFix Radiolucent Patient Immobilization System (K032156).