October 4, 2018

Qfix
Ms. Alexandra Low Smythe
Regulatory Affairs Specialist
440 Church Road
AVONDALE, PA 19311

Re: K182189
Trade/Device Name: Encompass™ SRS Headframe : Encompass MR SRS Headframe
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE
Dated: September 7, 2018
Received: September 10, 2018

Dear Ms. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182189

Device Name
Encompass™ SRS Headframe

Indications for Use *(Describe)*
The Encompass™ SRS Headframe 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 Headframe 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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SECTION 6. 510K SUMMARY

I. GENERAL INFORMATION

510k Number: K182189

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

Date Prepared: October 3, 2018

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

Contact Person: Alexandra Low Smythe
Regulatory Affairs Specialist

Qfix
440 Church Road
Avondale, PA 19311 USA
Phone: 610 268-0585 Ext 736
Fax: 610-268-0588

Device Name: Encompass™ SRS Headframe
Trade Name: Encompass™ SRS Headframe, Encompass™ SRS Headframe for Portrait, Encompass™ Headframe, SRS Headframe, Encompass™-S
Common Name: Stereotactic Radiosurgery (SRS) Immobilization 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, LHN, JAI, JAK, KPS, OUO

II. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING SUBSTANTIAL EQUIVALENCE

Indications for Use

The Encompass™ SRS Headframe 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 Headframe allows the patient to undergo

diagnostic imaging in the same position as that of the treatment position enabling more accurate radiation therapy.

Device Description

Qfix, has made a modification to its previously cleared Encompass™ SRS Immobilization System (cleared in K152321). In this modified variant of the Encompass™ SRS Immobilization System, the essential geometry of the head portion of the Encompass™ SRS Standalone Device is isolated to create a separate attachment which can be affixed to patient positioning devices that accept S-type thermoplastic masks, such as Qfix's Portrait™ Intracranial, Head and Neck Device (a device for use with S-type thermoplastics). Qfix intends to initially market the subject device for use with the Encompass™ SRS Fibreplast® System with optional IntegraBite™ (also cleared in K152321) and its devices which share a hole pattern and geometry with its Portrait™ Intracranial, Head and Neck Device. Examples of such devices include the kVue™ Portrait™ Intracranial, Head and Neck Insert and the Symphony® Portrait™ Transfer Device (cleared in K160627). This creates a flexible solution for a variety of imaging and radiotherapy treatment applications using stereotactic radiosurgery, such as radiation oncology and the treatment of non-cancerous conditions and malformations such as trigeminal neuralgia.

Predicate information

The subject device, the Encompass™ SRS Headframe, includes all of the device properties belonging to the predicate device, the Encompass™ SRS Immobilization System, also manufactured by Qfix. The predicate device information follows:

Predicate Device Name	FDA Clearance Number and Date	Product code	Manufacturer
Encompass™ SRS Immobilization System	K152321, cleared December 4, 2015	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 to Predicate Device

The Encompass™ SRS Headframe bears many of the same features as the predicate device, the Encompass™ SRS Immobilization System. The Encompass™ SRS Headframe 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 stereotactic radiosurgery (SRS). Both devices are non-sterile, reusable devices manufactured from composite materials. Both devices accept the same Encompass™ SRS Fibreplast® System patient immobilization masks. Both devices boast sub-millimetric accuracy.

Notably, the subject device is a removable attachment intended for use with other patient positioning devices that accept S-type thermoplastic masks, such as the

Portrait™ Intracranial, Head and Neck Device, allowing for improved setup flexibility for a variety of clinical applications as compared to the predicate device.

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.

- Verification of hardware specifications
- Accuracy validation via motion studies
- Ease of use/ergonomics assessments
- Verification of aluminum equivalence
- Verification of compatibility with optical tracking systems

Non-clinical bench testing and testing using healthy volunteers was conducted to support the continued applicability of the intended use and marketing claims of the predicate device with respect to this modification.

The Encompass™ SRS Headframe met all acceptance criteria for testing conducted and was appropriately validated per its intended use. The intended use and indications for use of the predicate device have not changed as a result of this modification.

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 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, the Encompass™ SRS Headframe, offers the following improvements over the predicate device, the Encompass™ SRS Immobilization System (cleared under K152321 on December 4, 2015).

- **The subject device is intended to be used in conjunction with other devices, allowing for improved setup flexibility for a variety of clinical applications.**
- **The subject device has a smaller footprint.**

- **The subject device enhances available treatment options using existing clinical infrastructure.**

The fundamental attributes of the subject device and the predicate device are the same.

- **Both devices have the same intended use.**
  The Encompass™ SRS Headframe has the same intended use as the Encompass™ SRS Immobilization System.
- **Both devices provide sub-millimetric immobilization for imaging and radiotherapy, including SRS.**
  The Encompass™ SRS Headframe, when used in conjunction with the Encompass™ SRS Fibreplast® System provides the same sub-millimetric immobilization as the Encompass™ SRS Immobilization System limiting motion to less than 1 mm in most clinical applications using stereotactic radiosurgery, such as radiation oncology and the treatment of non-cancerous conditions and malformations such as trigeminal neuralgia.
- **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.**
  The original Encompass™ SRS Immobilization System was intended to be used in conjunction with other devices in the Qfix product portfolio, such as the Encompass™ SRS Fibreplast® System with optional IntegraBite™, the kVue™ Couch Top, and various other patient positioning accessories. The Encompass™ SRS Headframe is intended to be used in conjunction with other devices in the Qfix product portfolio, such as the Portrait™ Intracranial, Head and Neck Device, the Encompass™ SRS Fibreplast® System with optional IntegraBite™, the kVue™ Couch Top, and various other patient positioning accessories.
- **Both devices have MR compatible variants.**
  Both the Encompass™ SRS MR Immobilization Standalone Device and the Encompass™ SRS MR Headframe are made of non-conducting composite materials and are considered MR Safe per ASTM F2503-13.

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 Encompass™ SRS Headframe does not raise new questions of safety or effectiveness and, therefore, is substantially equivalent to the marketed predicate device.