Qfix
% Alexandra Low Smythe
Senior Regulatory Affairs Manager and
Intellectual Property Specialist
440 Church Road
AVONDALE PA 19311

September 9, 2019

Re: K190668
Trade/Device Name: Encompass™ 15 Channel Head Coil, 3T
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: MOS
Dated: July 23, 2019
Received: July 24, 2019

Dear Alexandra Low 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/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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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)*
K190668

Device Name
Encompass™ 15 Channel Head Coil, 3T

Indications for Use *(Describe)*
The Encompass™ 15 Channel Head Coil is intended to be used in conjunction with a Magnetic Resonance Scanner for the MR examination of the human brain just before, during, and at the end of brain surgery. The Encompass™ 15 Channel Head Coil can also be used as a standard diagnostic head coil for diagnostic examinations and fMRI (Functional Magnetic Resonance Imaging). When used with magnetic resonance imaging systems, it is indicated for use as a diagnostic imaging device to produce transverse, sagittal, coronal and oblique images of the internal structures of the head. When interpreted by a trained physician, these images provide information that can be useful in determining diagnosis.

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: November 14, 2018

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

Contact Person: Alexandra Low Smythe
Senior Regulatory Affairs Specialist and Intellectual Property Specialist

Qfix
440 Church Road
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Phone: 610 268-0585 Ext 736
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Device Name: Encompass™ 15 Channel Head Coil, 3T
Trade Name: Encompass™ 15 Channel Head Coil, 3T
Common Name: 15 Channel Head Coil, Encompass SRS Coil
Classification Name: Magnetic Resonance Diagnostic Device
Regulation number: 21 CFR § 892.1000
Device Class: II
Product Code: MOS

II. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING SUBSTANTIAL EQUIVALENCE

Indications for Use

The Encompass™ 15 Channel Head Coil is intended to be used in conjunction with a Magnetic Resonance Scanner for the MR examination of the human brain just before, during, and at the end of brain surgery. The Encompass™ 15 Channel Head Coil can also be used as a standard diagnostic head coil for diagnostic examinations and fMRI (Functional Magnetic Resonance Imaging). When used with magnetic resonance imaging systems, it is indicated for use as a diagnostic imaging device to produce

transverse, sagittal, coronal and oblique images of the internal structures of the head. When interpreted by a trained physician, these images provide information that can be useful in determining diagnosis.

Device Description

Qfix and NORAS MRI products GmbH have jointly developed a head coil designed to enable MRI for diagnosis and to inform additional clinical actions, the Encompass™ 15 Channel Head Coil, 3T. The Encompass 15 Channel Head Coil is a diagnostic imaging device for use in 3T environments for obtaining diagnostic MR images to be used to inform procedures which use MR imaging to guide interventional procedures and other treatments. The Encompass 15 Channel Head Coil has been specifically designed to interface with the Encompass™ SRS Immobilization System (cleared with K152321 December 4, 2015).

The Encompass™ 15 Channel Head Coil is a ridged receive only coil featuring a 7 Channel Top Coil, an 8 Channel Bottom Coil, and an optional mirror holder. Imaging is performed with a 15-Channel "phased array" co-developed by Qfix and NORAS and manufactured by NORAS. The coils are mounted in a rigid Coil Frame and connection to the MRI is managed by the applicable MRI software. The Encompass™ 15 Channel MRI Head Coil has been designed for use with Siemens Healthineers MAGNETOM 3T systems e.g. MAGNETOM Skyra.

Encompass™ 15 Channel Head Coil has been optimized for use with the Encompass™ SRS Immobilization System. The use of the Encompass™ 15 Channel Head Coil together with the Encompass™ SRS Immobilization System allows immobilization of the patient while obtaining diagnostic MR images to be used to inform procedures which use MR imaging to guide interventional procedures and other treatments.

Predicate Information

Qfix believes that the subject device, Encompass™ 15 Channel Head Coil is substantially equivalent to the following head coil within the meaning of the Safe Medical Devices Act of 1990.

Predicate Device Name	FDA Clearance Number and Date	Product code	Manufacturer
NORAS OR Head Coil 3T	K091546, cleared June 24, 2009	MOS	NORAS MRI products GmbH

The Encompass™ 15 Channel Head Coil and the NORAS OR Head Coil 3T are both intended to be used in surgical settings for diagnostic evaluation of the brain and obtaining diagnostic MR images to be used to inform procedures which use MR imaging to guide interventional procedures and other treatments. 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™ 15 Channel Head Coil bears many similarities to its predicate, the NORAS OR Head Coil. The Encompass™ 15 Channel Head Coil has a similar Intended Use and purpose as the predicate device. Both the subject device and the predicate device can provide diagnostic information about the head to inform interventional procedures.

The subject device offers the following improvements over the predicate.

- The housing of the subject device is made of different materials than the predicate device.
- The subject device has 15 channels while the predicate device has 8.
- The subject device is intended to be used independently or in conjunction with the Encompass SRS Immobilization System. The use of the subject device with immobilization devices in general increases SNR due to motion reduction for visualization of fine details. The predicate device is not compatible with immobilization devices.
- The subject device offers different adjustments to allow for being as close as possible to patient without disturbing anatomy for improved SNR.
- The subject device offers improved homogeneity across the entire head.
- The subject device features additional considerations for patient comfort, including a patient viewing window and accomodations for a mirror in two orientations.

Performance Standards and Testing

Testing and analysis have been conducted to show that the verification, validation, and safety requirements have been met per the FDA as established standards. The subject devices have been tested in accordance with FDA recognized NEMA standards for the measurement of performance and safety parameters. 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 cycle and continuing throughout the development of the product. Qfix and NORAS adhere to recognized and established industry standards, such as the IEC 60601-1 series, to minimize electrical and mechanical hazards. This device was tested on 3T Siemens Healthineers MANGETOM MRI scanners and the performance of this device can be considered safe when used with available MAGNETOM 3T systems e.g. MAGNETOM Skyra.

Non-clinical bench testing and customer validation was conducted to support the intended use and to confirm that technological differences do not raise any new issues of safety or effectiveness over the predicate.

Clinical Tests

No clinical tests were conducted to support the subject device and the substantial equivalence argument, however clinical images were provided to support the Encompass™ 15 Channel Head Coil.

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 & NORAS adhere 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 procedures for which the subject device is intended to be used.

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 Conclusions

The subject device, Encompass™ 15 Channel Head Coil, is optimized for use with the Encompass SRS Immobilization System for obtaining diagnostic MR images to be used to inform procedures which use MR imaging to guide interventional procedures and other treatments. While the predicate device, NORAS OR Head Coil 3T, is optimized for its usefulness in interventional surgery applications, both devices are head coils and the fundamental attributes of the subject device and the predicate device are the same.

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 believes the Encompass™ 15 Channel Head Coil does not raise new questions of safety or effectiveness and, therefore, is substantially equivalent to the marketed predicate device.