April 4, 2025

Foqus Technologies Inc.
Sadegh Raeisi
Official Correspondent
The Tannery, 151 Charles St W Suite# 199
Kitchener, ON N2G1H6
Canada

Re: K241982
Trade/Device Name: DeepFoqus (DeepFoqus-Accelerate)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: February 28, 2025
Received: March 3, 2025

Dear Sadegh Raeisi:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Daniel M. Krainak, PhD
Assistant Director
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241982

Device Name
DeepFoqus (DeepFoqus-Accelerate)

Indications for Use *(Describe)*
DeepFoqus-Accelerate is a stand-alone software solution intended to be used for acceptance, enhancement, and transfer of brain MRI images in DICOM format. It can be used for reconstruction of non-contrast enhanced MRI images acquired with 1.5T or 3T Siemens and GE scanners using Sagittal, Axial, or Coronal T1, T2, or FLAIR sequences.
DeepFoqus-Accelerate is intended to be used on adult scans only and not intended for use on mobile devices.

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) #: K241982

Prepared on: 2025-04-04

1.0 Contact Details 21 CFR 807.92(a)(1)

Applicant Name	Foqus Technologies Inc.
Applicant Address	The Tannery, 151 Charles St W Suite# 199 Kitchener ON N2G1H6 Canada
Applicant Contact Telephone	647-4254787
Applicant Contact	Mr. Sadegh Raeisi
Applicant Contact Email	sadegh.raeisi@foqus.ca

2.0 Device Name 21 CFR 807.92(a)(2)

Device Trade Name	DeepFoqus (DeepFoqus-Accelerate)
Common Name	Medical image management and processing system
Classification Name	Automated Radiological Image Processing Software
Regulation Number	892.2050
Product Code(s)	QIH

3.0 Legally Marketed Predicate Devices 21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K210999	SwiftMR	LLZ

4.0 Device Description Summary 21 CFR 807.92(a)(4)

DeepFoqus-Accelerate is an AI-powered MRI software that accepts up to 4x accelerated scans and reconstructs them to yield acceptable scans when compared to standard unaccelerated scans.

DeepFoqus allows input of HDF5 and DICOM files, acquired with common MRI machines, containing accelerated T1, T2, and FLAIR image sets. Once inputted, DeepFoqus performs a series of reconstruction steps to produce clinical-quality scans from the undersampled data in the phase encoding direction.

DeepFoqus-Accelerate uses AI and machine learning models to reconstruct MRI images from up to 4x accelerated MRI scans. The models combine various signal processing and machine learning techniques including several convolutional neural network (CNN) and U-net architecture models.

The full pipeline involves the following steps:

1. Ingestion of MRI scans as k-space and DICOM files.
2. Preprocessing steps to ensure that the input is in a standard format and meets acquisition requirements.
3. Processing through a pipeline that combines a collection of machine learning and signal processing modules that ensures that an appropriate range of fine-tuned models is applied to reconstruct a final volume.
4. Post-processing steps which include adjustments for windowing and image size.
5. Conversion of the final volume to DICOM format.

The overall pipeline has been trained to minimize the distance between reconstructed final images and standard accelerated scans. Training has been conducted on a range of datasets which include diverse magnet strengths, sequences, manufacturers, and image orientations.

The software provides a workflow for an MRI/Radiology Technologist to:

1. Input undersampled data into the software through a user interface
2. Start a processing pipeline and observe progress
3. Export reconstructed data for use in downstream applications

5.0 Intended Use/Indications for Use 21 CFR 807.92(a)(5)

DeepFoqus-Accelerate is a stand-alone software solution intended to be used for acceptance, enhancement, and transfer of brain MRI images in DICOM format. It can be used for reconstruction of non-contrast enhanced MRI images acquired with 1.5T or 3T Siemens and GE scanners using Sagittal, Axial, or Coronal T1, T2, or FLAIR sequences.

DeepFoqus-Accelerate is intended to be used on adult scans only and not intended for use on mobile devices.

6.0 Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use for the predicate device and the subject device are the same.

7.0 Technological Comparison 21 CFR 807.92(a)(6)

DeepFoqus-Accelerate is substantially equivalent to AIRS Medical SwiftMR (K210999).

Both the Subject and Predicate devices are similar in terms of technology and intended use. Both software systems contain deep learning algorithms which produce automatic images quality enhancement. Both devices are only intended to be used for professional purposes and are not intended for use on mobile devices. The workflow between the two systems is the same:

* MR images are uploaded into the software

* The software uses a deep learning model to enhance the images

* The images can be downloaded in DICOM format from the software

Neither software product directly interfaces with the MRI or other data collection equipment.

The primary difference between the Predicate and Subject device is the reconstruction/enhancement algorithm. The Predicate implements an image enhancement algorithm using convolutional neural network-based filtering. The Subject implements an image reconstruction algorithm using ensembles of deep learning models. Ensembling aggregates several model architectures in order to produce a single reconstruction of accelerated image data.

This difference was verified and validated using the following methods:

* Performance and comparison evaluations (PSNR, HaarPSI, SSIM)

* Phantom Bench testing (geometric accuracy, intensity uniformity, percentage ghosting, signal-to-noise ratio, resolution, and low-contrast detectability)

* Artifact assessment (quantitative (SSIM) and qualitative assessment of images which are expected to have artifacts)

* Clinician evaluation (reconstruction quality score)

The essential underlying device outputs and use are the same. The intended uses are equivalent. Direct comparison of major functionality was possible and showed largely identical results.

The above comparison to the Predicate device in conjunction with the design verification and validation activities described in this 510(k) submission support substantial equivalence of SwiftMR.

8.0 Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Software verification, validation, and standards compliance were all relied on in the determination of substantial equivalence.

Standards Compliance

The subject device is in conformity with the requirements of the following:

* ISO 14971:2019

* IEC 62366-1:2015+AMD1:2020

* IEC 62304:2006/A1:2016

* NEMA PS 3.1-3.20 2022d

* ISO 15223-1 (2021)

* AAMI TIR 57:2016

* AAMI TIR 97:2019

* AAMI SW96:2023

Software Verification

The following types of verification were performed, all testing met acceptance criteria.

* Software code review

* Static code analysis

* Unit verification

* SOUP verification

* Architecture and software requirements reviews

* Software functional verification

* Penetration testing, secure code review, and dependency vulnerability scanning

Software Validation

The following types of validation were performed, all testing met acceptance criteria.

* Analytical performance validation - Three specific metrics were used to demonstrate acceptable performance and equivalence with the predicate device - Structural Similarity Index Measure (SSIM), Peak Signal to Noise Ratio (PSNR), Haar wavelet-based perceptual similarity index and (HaarPSI)

* Phantom bench testing - Done to ensure that the reconstruction algorithm meets the necessary quality standards according to “Large and Medium Phantom Test Guidance for the ACR MRI Accreditation Program”.

* Artifact assessment - Conducted to demonstrate the robustness of the AI-based DeepFoqus-Accelerate reconstruction against common MRI artifacts, ensuring that no additional reconstruction errors are introduced.

* Clinical performance validation - Radiologists reviewed a sample of diverse accelerated scans (including pathological and non-pathological brains) to determine whether the accelerated scans were equivalent to the ground truth.

* User acceptance testing and summative evaluation - Radiology technologists, IT administrators, and radiologists reviewed critical tasks inherent in the software and user requirements for acceptability.

The design verifications conducted support the conclusion that DeepFoqus-Accelerate performs as intended. The design validation, along with comparison and performance evaluations, support the conclusion that DeepFoqus-Accelerate performs comparably to the predicate device that is currently marketed for the same intended use.