September 8, 2023

FHC, Inc.
Kelly Moeykens
QSO & Quality/Regulatory Manager
1201 Main Street
Bowdoin, Maine 04287

Re: K231141
Trade/Device Name: STarFix Designer Software (C0265)
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: QRI, HAW
Dated: August 9, 2023
Received: August 10, 2023

Dear Kelly Moeykens:

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,

Adam D. Pierce -S
Digitally signed by Adam D. Pierce -S
Date: 2023.09.08 11:37:42 -04'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231141

Device Name
STarFix Designer Software (C0265)

Indications for Use *(Describe)*
The STarFix Designer Software is part of the WayPoint Stereotactic System. The WayPoint Stereotactic System is intended to be used with commercially available stereotactic system for neurological procedures which require the accurate positioning of microelectrodes, stimulating electrodes, or other instruments in the brain or nervous system.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary

1. Submitter's name, address, telephone number, a contact person, and the date the summary was prepared:

FHC, Inc.
1201 Main Street
Bowdoin, ME-04287
Tel: 207-666-5651
Fax: 207-666-8292

Contact: Kelly Moeykens
Date: 04/20/2023

2. Name(s) of the Device:

Proprietary/Trade Name:	STarFix™Designer STarFix™Designer, SFD or C0265 or Stereotaxis
Common Name:	Planning Software
Regulation Number	
Regulation Name:	Neurological Stereotaxic Instrument
Classification Panel	Neurology
Product Code:	QRI
Regulatory Class:	II

3. Legally Marked Predicate Device to which the submitter claims substantial equivalence:
The STarFix™Designer is substantially equivalent to FHC, Inc.'s Voxim and WayPoint™ Planner Planning Software, part of the WayPoint™ Stereotactic System (K092192); decision date: February 12th 2010, product code: HAW

4. Description of device:

FHC, Inc. STarFix™ Designer software is an advanced image-based neurosurgical planning software application designed for generating patient specific frames (FHC, Platform) primarily for Deep Brain Stimulation (DBS) Proedures and stereo-electroencephalography (SEEG) by means of the WayPoint™ Stereotactic platforms.

The STarFix™ Designer offers the following core features:

- Image import and registration
  - Open and manipulate CT and MR images for surgical planning
  - Rigid registration between CT and MR images, with user-selected reference scan of either modality.

- Automatic localizer extraction
  - Extract localizers from preoperative CT manually or automatically
  - Manually place localizers on MR scans
  - Manual refinement of localizer position
- Patient specific 2D and 3D visualization of anatomical landmarks: AC, PC, MP
- Trajectory planning
- DBS STarFix™ Platform frame modeling
- Multi-Oblique STarFix™ Platform frame modeling
- Export and import planning data, including images, for transfer on another computer or to be saved for easy reference during the surgery
- Save the plan any time during the planning session

The STarFix™ Designer provides a modern design, built to ease user interaction, and allow fast and efficient planning for the WayPoint™ Platforms and ultimately, the implantation of DBS electrodes. With safety as a primary concern, all planning elements need to be verified and marked explicitly before a platform model can be built. The user interface is guiding the user through the necessary planning steps, by using numbered menus and intuitive labeling, along with a minimum of application settings and common actions arranged in the form of a toolbar dedicated to either 2D or 3D operations.

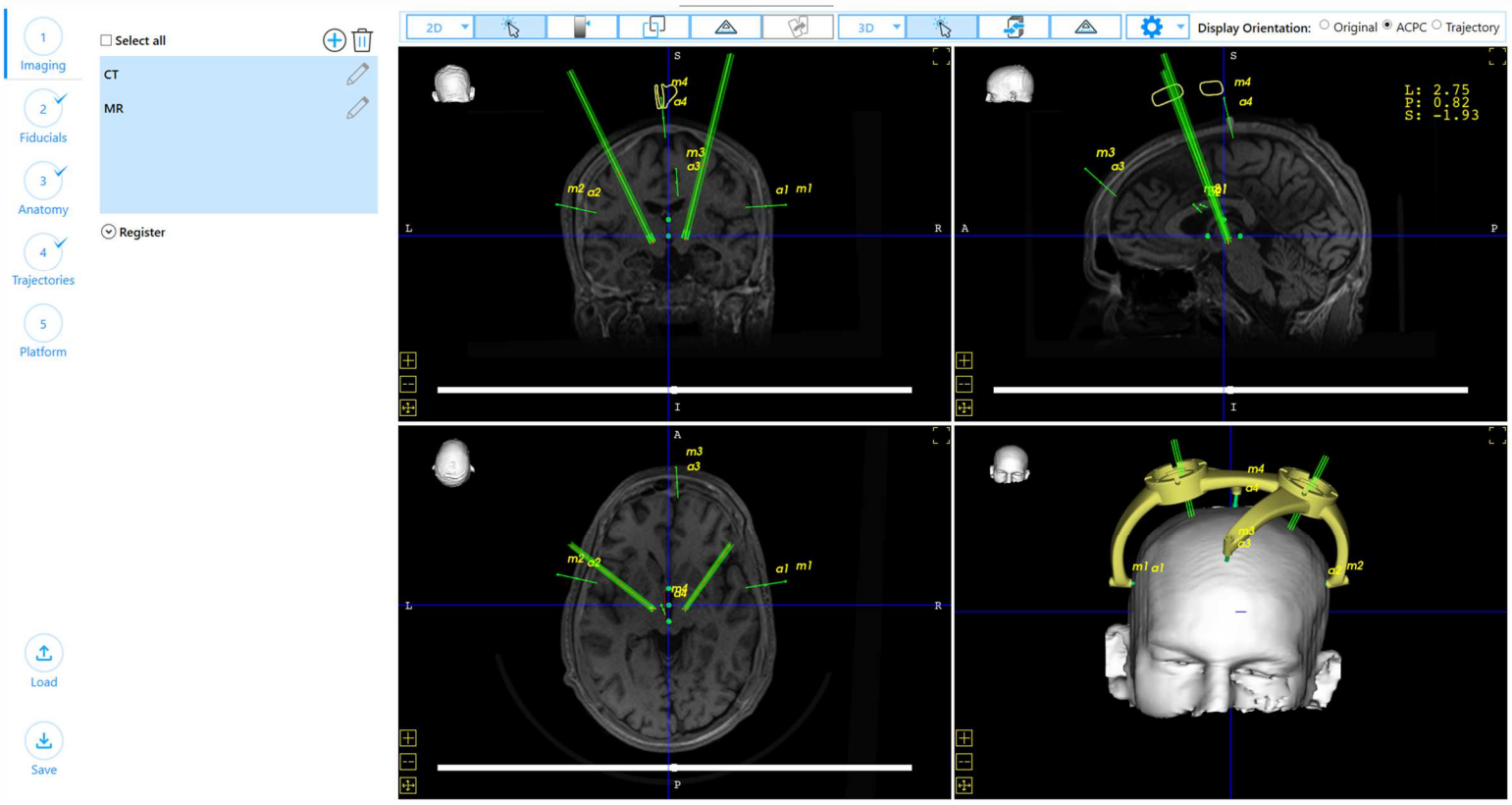

Figure 1 : DBS planning session using the bilateral platform.

5. Statement of Intended Use:

STarFix™Designer software is intended to be used by a neurosurgeon, neurologist or clinical neurophysiologist to plan and monitor positioning of microelectrodes, stimulating electrodes, or other instruments in specific anatomical structures in brain or nervous system.

Statement of Indications for Use:

The STarFix™Designer is part of the WayPoint™ Stereotactic System. The WayPoint™ Stereotactic System is intended to be used with commercially available stereotactic systems for neurosurgical procedures which require the accurate positioning of microelectrodes, stimulating electrodes, or other instruments in the brain or nervous system.

6. Comparison of Technological Characteristics to Predicate Device

The technological characteristics of the STarFix™ Designer are the same as those in the predicate device. There is no new technology, materials or method of manufacture introduced. A summary of similarities in the specifications between the STarFix™ Designer and its predecessor is provided below.

Table 2: Similarities between STarFix™Designer, Waypoint Planner and Voxim microTargeting™

Component **Section**	**Feature**	**Subject Device:** STarFix™™ Designer	**Predicate:** Waypoint™ Planner	**Predicate:** Voxim
Imaging Load images, preview	CT loading	Yes	Yes	Yes, load patient datasets.
	MRI loading	Yes	Yes	Yes, load patient datasets.
Aligning images	Manual pre-align: Align/Rotate	Yes	Yes	Yes
	Automatic Registration	Rigid Registration by Intensity	Rigid Registration by Intensity, Registration by points, Registration by device	Yes, automatic matching, imaging device referential, or frame registrations.

	Incremental registration – use previous registration step as a base for a new registration step	Yes	Yes	No
Viewing Images -2D	Checkerboard, Lens to check accurate alignment	Yes	Same	Yes, shade feature
	Brightness/Contrast	Yes	Same	Yes, grayscale tool.
	Measurement	Yes, distance and angles	Same	Yes, distance, angles, surface
Viewing Images -3D	3D volume reconstruction	Yes	Yes	Yes
	Thresholding	Yes, lower and upper limit	Yes, lower limit	Yes, lower and upper limit
	Solid/ Slice views	Yes	Yes	Yes, solid and surface cut
	Distance measurement	Yes	Same	Yes
Fiducials Anchor Detection	Automatic Anchor detection	Yes	Same	Yes
	Seed and search (semi-automatic search)	Yes	Same	No
	Manual placement	Yes	Same	Yes
Anatomy	AC, PC, MP manual point placement	Yes	Same	Yes

Point Selection	Display of AC-PC Length	Yes	Yes	Yes
Trajectories Adding trajectories	Editing of trajectory name, entry and target coordinates	Yes	Yes	Yes, trajectory parameter panel
	Mirroring an existing trajectory with respect to the mid-plane	Yes	Same	Yes
	Using templates to add trajectories	Yes	Same	No
	Displaying distance to target	Yes	No	Yes
	Surgeon's eye view (trajectory view)	Yes	Same	Yes
Platform STarFix™ Platform – Unilateral or Bilateral	Select platform model	Yes	Same	Yes
	Automatically sort anchors	Yes	Yes	Yes
	Automatically sort trajectories	Yes	Yes	Yes
	Specifying Platform height	Yes	Same	Yes
	Building the platform	Yes	Same	Yes
Multi-Oblique Platform	Select platform model	Yes	Same	No
	Edit connections	Yes	Yes	No

		Specifying hub height	Yes	Yes	No
		Building the platform	Yes	Same	No
Data Export	Exporting the production file	Edit the patient details and save the file to disk	Yes	Same	Yes
	Plan files	Save the current plan to disk	Yes	Yes.	Yes.

8. Substantial Equivalence statement:
The STarFix™ Designer Software System is substantially equivalent in design, construction, materials, intended use and performance characteristics to its predicative devices, FHC, Inc.'s Voxim and WayPoint™ Planner Planning Software, part of the WayPoint™ Stereotactic System (K092192); decision date: February 12th 2010.

9. Performance Data:
Performance data of the STarFix™Designer Software System is documented in the verification and validation reports. Software regression test results show the system to be the equivalent to the predicate system.

Test	Test Method Summary	Results
Software regression testing	The internally created software regression test protocol is based on the workflow established in the Usability specification of the predicate device. It is performed iteratively at each software release per IEC 62304. All major and minor software functions were tested iteratively prior to each	All major areas of software functionality were confirmed for the subject device. No remaining bugs had a risk level of greater than Acceptable as defined by risk management plan. Over the course of its life-cycle, the predicate device received similar treatment with respect to bug fixes, bug risk acceptance, software

	release of a new software revision. Additionally, bugs fixed since the previous round of regression testing were assessed for effectiveness and risk.	releases, and regression testing. As such, substantive equivalence is established.

10. Conclusion

Based on the non-clinical performance data performed comparing the STarFix™ Designer software to the predicate device (Voxim and WayPoint Planning Software), it is concluded that the subject device is as safe and effective as the predicate device.