December 20, 2018

FHC, Inc.
Kelly Moeykens
Quality Systems Officer
1201 Main Street
Bowdoin, Maine 04287

Re: K183123
Trade/Device Name: microTargeting Guideline 4000 5.0 System
Regulation Number: 21 CFR 882.1330
Regulation Name: Depth Electrode
Regulatory Class: Class II
Product Code: GZL
Dated: November 6, 2018
Received: November 13, 2018

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/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,

Jay R. Gupta -S

For Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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)*
K183123

Device Name
microTargeting™ Guideline 4000 5.0 System

Indications for Use *(Describe)*
The microTargeting™ Guideline 4000 5.0 System is intended to record and stimulate electrophysiological activity, as well as aid in the accurate placement of electrodes and other instruments.

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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SPECIAL 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:11/01/18

2. **Name(s) of the Device:**

Proprietary/Trade Name:	microtargeting™ Guideline 4000™ 5.0 System
Common Name:	Guideline 5 or GL5 or Guideline 4000™ 5.0™ or MT-LPP or Intraoperative neurophysiological recording and stimulating device
Classification Name:	Depth Electrode
Regulation #	21 CFR 882.1330
Regulatory Class:	II
Product Code:	GZL

3. **Legally Marked Predicate Device to which the submitter claims substantial equivalence:**

The microtargeting™ Guideline 4000™ 5.0 System is substantially equivalent to FHC, Inc.'s microTargeting® Guideline 4000 (K071364); decision date: July 25th 2007, product code: GZL.

4. Description of device:

The microtargeting™ Guideline 4000™ 5.0 System is an electrophysiological recording and stimulation system designed primarily for functional neurosurgery procedures.

The microtargeting™ Guideline 4000™ 5.0 System provides:

- High quality and research-grade recordings on both microelectrodes and macroelectrodes, including low-frequency signals on externalized DBS leads
- Improved signal quality
- Decreased Noise susceptibility
- Improved user experience with redesigned software
- New intraoperative data analysis options
- Updated user interface to support touch screens and multiple high-resolution monitors

Additionally, Guideline 5 interface provides unprecedented simultaneous constant-current and constant-voltage stimulation capabilities that include multiple weighted sources and return paths as well as complex and arbitrary stimulation waveforms. Together, these capabilities result in the output of advanced stimulation protocols, including current steering. The software provides an intuitive patient management system, as well as advanced visualization and analysis methods for both single-unit recording and low-frequency signals (LFP, SEEG etc.).

The Guideline 5 offers neurosurgical teams a powerful microelectrode recording/stimulating system in a compact, streamlined package. It offers fully integrated stimulation and impedance check capabilities on all channels, in addition to one-click recall of user preferences and side-by-side review of all recorded snapshots.

As shown below, a fully configured system consists of a Core Module, a notebook PC, an 8-channel UE interface unit, a remote, an optional second 8-channel LF interface and an optional synchronization unit.

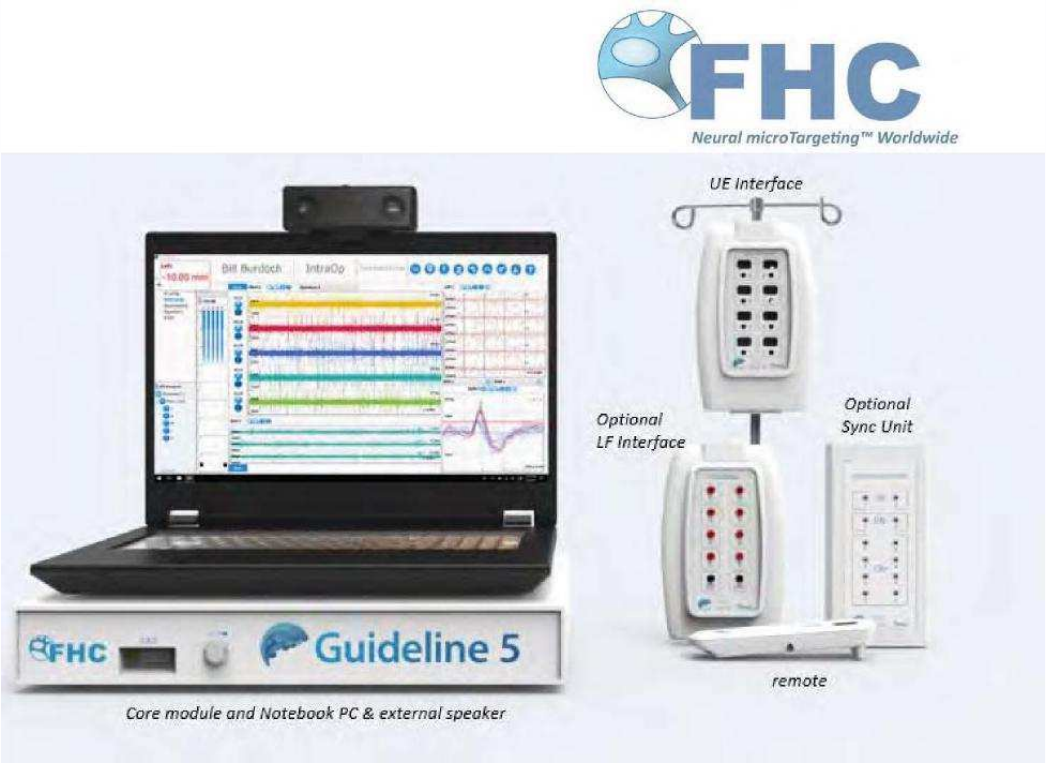

Figure 1 : A fully configured Guideline 5 system.

Individual components which comprise the Guideline 5 system are listed in the table below:

Table 1: List of components of Guideline 5 system

Component Name	Catalog Number	Description	Classification
Main Processing Unit	C0215	Guideline 5 Main Unit	Core Component
Guideline PC	C0216	Guideline 5 Notebook	Core Component
Ethernet Cable	C0234	Ethernet Cable	Core Component
UE Interface	C0219	Microelectrode head-stage	Core Component
LF Interface	C0220	Low Frequency Signal head-stage	Accessory
Software	C0217	Guideline 5 Software Application	Core Component
Secondary Interface Processing Card	C0218	Interface Processing Card (factory or field installed)	Variant (internal)
Interface Digital Cable	C0221	3m Interface Cable	Core Component
Motor	C0235	microTargeting Power Assist Unit (existing medical device, not within the scope of these design inputs)	Accessory

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mT Controller Card	C0223	Integrated microTargeting Controller	Variant (internal)
Remote Control	C0222	Guideline 5 Remote Control	Core Component
Breakout Box	C0224	Synchronization Unit	Accessory
HD Digital Cable	C0225	1m Synchronization Unit Cable	Accessory
3m Patient Lead	C0230	3m UE Cable	Consumable
1.5m Patient Lead	C0231	1.5m UE Cable	Consumable
Interface pole mount	C0233	Interface Pole Mounting Bracket	Accessory
Speaker	C0237	High Performance Speaker	Core Component

The Guideline 5 has full featured multi-source stimulation capabilities. Stimulation modes of constant voltage or constant current mode are available with a compliance voltage of ±14V. The UE Interface is capable of microstimulation (±100µA max) through the microelectrode as well as macrostimulation (±10mA max) through the macro-contact. During stimulation, the voltage applied to the electrode is monitored and displayed constantly. The LF provides macro-stimulation. Every channel has its own stimulation circuit, allowing the Guideline 5 to perform the complex simultaneous multi-channel, multi-return stimulation protocols required for current shaping and steering. Channels not involved in the stimulation continue to record activity while an adaptive suppressor minimizes stimulus artifacts.

Integrated Impedance Check functionality for microelectrodes, macro-contacts and LF electrodes can be performed easily for monitoring the state of all connected electrodes. Measurement frequency and duration are user adjustable. The low measurement current of 1µApp minimizes any effect of the measurement on microelectrode properties. Simultaneous measurement of all channels provides quicker results. An automated power on self-test verifies proper operation and calibration of all stimulation and impedance check circuitry prior to every use of the Guideline 5 system.

The Guideline 5 is capable of recording any or all activity on an event-by-event basis or continuously. Recorded waveforms can be reviewed and analyzed intraoperatively or post-operatively. Sample Matlab™ scripts provided allow for more advanced analyses of electrode and auxiliary data suitable for research applications.

5. **Statement of Intended Use:**

The microtargeting™ Guideline 4000™ 5.0 System is intended to be used by a neurosurgeon, neurologist or clinical neurophysiologist to accurately position depth electrodes during functional neurosurgical procedures. In addition, when external devices such as EMGs or accelerometers are connected to the Guideline 4000™ 5.0, the system is capable of displaying and recording the activity from these external devices. The Guideline 4000™ 5.0 is also intended to be used in functional neurosurgical procedures for physiological mapping of the brain and nervous system; thereby aiding in the accurate placement of electrodes or other instruments.

Statement of Indications for Use: The Guideline 4000™ 5.0 is intended to record and stimulate electrophysiological activity, as well as aid in the accurate placement of electrodes and other instruments.

6. **Comparison of Technological Characteristics to Predicate Device:**

The technological characteristics of the Guideline 4000™ 5.0 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 Guideline 4000™ 5.0 and its predecessor is provided below.

Table 2: Similarities between Guideline 4000 and Guideline 4000™ 5.0

Component	Section	Feature	Guideline 4000	Guideline 4000™ 5.0
Signal Amplifier	**Signal Conditioner**	Gain	28.3 - 3764x (Analog)	UE: 5.9 - 214x (+3x optional), LF: 1,2,4,6,12,24x (Analog)
		High Pass/Low Pass Filters	Continuous; 0-1,000/3,000-20,000	Continuous: 0-10,000Hz
	Stimulation circuit	Isolated	Yes	Yes
		Stimulator Type	Constant Current & Voltage	Same
		Settings control	Settings controlled via hardware and software. Activation still only a hardware function.	Same
		Waveform Displayed?	No	Same
		Waveform Type	Arbitrary, Unipolar or Bipolar Square Wave	Same
	Stimulation Modes	Micro	Yes	Same

		Macro	Yes	Same
	Stimulus Controls	Max Micro Stim Amplitude	100 uA	Same
		Max Macro Stim Amplitude	10 mA	10mA
		Frequency	Up to 300 Hz	Up to 300Hz
		Pulse Duration	.05, .1, .2, .5, 1 ms	Continuous up to 3.0 mS (50% duty cycle max)
		Train Duration	Manual, 0.5 to 20 s	Manual, 0.5s - 60 s
	Adaptive Noise Filter	Available	Yes	Same
	Data Acquisition	Pipeline	USB2.0	TCP/IP
	Pre-amp	Built in gain	28.3 x	N/A
		Max Distance to patient	3 m	Same
		Max # of Channels	10	8(16 with two interfaces)

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	Impedance Check	Activation controlled by	Software	Same
		Waveform used	Sinewave	Composite Waveform, Sine @ 200Hz and sine @ 1000Hz
		Measurement Range	10kOhms to 10MOhms	100 Ohms - 5MOhms
		Resolution	2 significant digits	Same
	Remote	Available	Yes	Same
		Stimulation Activation	Yes	Same
		Stimulus Amplitude Selector	Yes	Same
		Microphone	Yes	Same
		Impedance Check Activation	Yes	Same
	Action Indicators	General Fault	Visual Alarm	Same
		Stimulation Error	Visual and Audio Alarm	Same
		Stimulation Activated	Visual and Audio Alarm	Same

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		Impedance Overage	Visual Alarm	Same
Audio Amp	**Source**	Un-conditioned Signal	No	Yes
		Conditioned Signal	Yes	Yes
	Audio	Baseline Suppressor	Yes	Same
		Bass Control	Yes	Same
		Treble Control	Yes	Same
		Graphic Equalizer	No	Same
	Volume	Headphone Control	No, not applicable	Yes
		Speaker Control	Yes	Same
		System Mute	Yes	Same
	Inputs	Microphone	Yes	Same

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	Outputs	Headphone Speakers	No Yes	Yes Same
Aux Input Unit		Max number of channels	4 analog, 2 digital	2 analog, 2 high speed digital, 2 byte digital
Computer System	**CPU Speed**	At least 1.0 GHz	2 GHz dual core	Intel, Core I7 (min)
	RAM	At least 256 MB	2 GB	8GB
	Monitor	At least 17" w	wide screen 17" UXGA	15.6" diag, 1920x1080 resolution
	Touchscreen	Yes (option)	No	Multipoint
	CD-RW	Yes	Yes	No

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	Storage Drive	Yes, Size	No	Yes (1TB min)
Recording Software	**Data Tags**	Voice Tags	Yes	Same
		Custom Text Tags	Yes	Same
		Preloaded Test Tags	No	Same
		Drive Depth	Yes	Same
	Waveform Display	Fast (Spike) - Allows user to focus on single event if needed	Yes	Same
		Slow (Continuous) - default waveform displayed for each channel.	Yes	Same
		Spectrogram	No	Yes
	Spike Discrimination	Window	Yes	Same
		Level	Yes	Same

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	Waveform analysis	Template Matching	Yes	No	

7. Nonclinical performance Data:

Performance data of the microTargeting™ Guideline 4000™ 5.0 System is documented in the verification and validation reports. Electrical Safety Test, Mechanical Integrity test, Macrostimulation test, Microstimulation test and Software regression test results show the system to be the equivalent to the predicate system.

Test	Test Method Summary	Results
Electrical Safety	Electrical Safety consistent with IEC 60601 (Class 1 ME Equipment) Internal Testing based on IEC 60601 protocols. 60601-1 Electrical Safety Testing Performed Externally by 3rd Party entity.	Both internally and externally performed electrical safety testing on subject device per standard IEC 60601 passed the acceptance criteria necessary for establishing basic safety. The subject and predicate device were both exposed to the same 60601-1 electrical safety testing therefore a substantive equivalence is established.
Mechanical Integrity	Mechanical Strength and Integrity testing consistent with standard IEC 60601 Internal Testing based on IEC 60601 protocols. 60601-1 Mechanical Strength Testing Performed Externally by 3rd Party entity.	Both internally and externally performed mechanical strength testing on subject device per standard IEC 60601 passed the acceptance criteria necessary for establishing basic safety. The subject and predicate device were both exposed to the same 60601-1 mechanical strength testing therefore a substantive equivalence is established.
Macro Stimulation	The test method employed is an internally generated protocol in which the subject device is assessed on three key parameters relevant to the safe and effective delivery of therapeutic electrical stimulus. These parameters include: -Accurate output frequency -Accurate pulse duration -Accurate stimulus amplitude	The subject devices met the acceptance criteria necessary for establishing accuracy of stimulator outputs to within ±10% of the User Interface set point for frequency, pulse duration, and amplitude. Given the predicate device provides the same accuracy, a substantive equivalence is established.

	Each parameter is adjusted via the software user interface. Each parameter is then measured using a NIST traceable oscilloscope with the subject device's output terminated with precision resistive loads which act as microelectrode analogs.	
Micro Stimulation	The test protocol used for Macro Stimulation mode also applies to Micro stimulation with the exception of the latter outputs an order of magnitude lower stimulus amplitude.	The subject devices met the acceptance criteria necessary for establishing accuracy of stimulator outputs to within ±10% of the User Interface set point for frequency, pulse duration, and amplitude. Given the predicate device provides the same accuracy, a substantive equivalence is established.
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 release of a new software revision. Additionally, bugs fixed since the previous round of regression testing were assessed for effectiveness and risk.	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 releases, and regression testing. As such, substantive equivalence is established.

8. Substantial Equivalence statement:

The microTargeting™ Guideline 4000™ 5.0 System is substantially equivalent in design, construction, materials, intended use and performance characteristics to its predicative devices, FHC, Inc.'s microTargeting® Guideline 4000 System (K071364), which was cleared under 510(k) K071364, July 25th, 2007.