DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 12, 2014

Alpine Biomed ApS
Seamus O'Connor
Tonsbakken 16-18
DK-2740 Skovlunde, Denmark

Re: K140680
Trade/Device Name: Leadpoint Focus
Regulation Number: 21 CFR 882.1330
Regulation Name: Depth electrode
Regulatory Class: Class II
Product Code: GZL
Dated: November 10, 2014
Received: November 12, 2014

Dear Mr. O'Connor:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140680

Device Name
Leadpoint Focus

Indications for Use *(Describe)*
The Leadpoint microelectrode targeting system is intended to assist in neurosurgical procedures where recording of neuronal activity and stimulation of brain neurons will aid in the placement of depth electrodes.

The Leadpoint microelectrode targeting system is intended to be used in the operating room by a neurosurgeon, neurologist, or clinical neurophysiologist.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5 510(k) Summary

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510(k) Summary

510(k) Number: **K140680**

10 December 2014

Submitter's name:

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Contact Person:

Seamus O'Connor,
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Trade name:

Leadpoint Focus

Device Class

Class II

Classification name:

Depth electrode.

Product code and Regulation:

GZL 21CFR 882.1330

Predicate devices:

The Leadpoint Focus is substantially equivalent to the predicate device K071364 Guideline 4000 from FHC, Inc.

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510(k) Notification for Leadpoint Focus

Intended use / Indications for use:

The Leadpoint Focus microelectrode targeting system is intended to assist in neurosurgical procedures where recording of neuronal activity and stimulation of brain neurons will aid in the placement of depth electrodes.

The Leadpoint Focus microelectrode targeting system is intended to be used in the operating room by a neurosurgeon, neurologist, or clinical neurophysiologist.

Device Description:

Intraoperative microelectrode recording (MER) has been introduced to improve the target localization during stereotactic surgery. The Leadpoint Focus is a MER system which consists of the Leadpoint Focus Software, Focus Hardware, a Macro Stimulator, a MER amplifier and a sterile interconnection cable (MER Cable) that connects the system to a Microelectrode. The Microelectrode is supplied by another manufacturer and is not part of the Leadpoint Focus system.

The recognized upper limit for safe stimulation is 30µC/cm^2 per phase.

Microelectrode Connection

A MER Cable is an electrode cable composed of strands of insulated electrical conductors intended to connect a Microelectrode from a patient to the Leadpoint Focus system.

The MER Cable is an optional consumable part.

The MER cable is for single use only and delivered sterile.

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510(k) Notification for Leadpoint Focus

Summary of Technological Characteristics comparison

Characteristic	Alpine Biomed ApS Leadpoint Focus (This submission)	FHC, Inc. Guideline 4000 (K071364)	Discussion of Differences
Indications for Use			
1.1 Intended Use / Indications for Use	The Leadpoint Focus microelectrode targeting system is intended to assist in neurosurgical procedures where recording of neuronal activity and stimulation of brain neurons will aid in the placement of depth electrodes. The Leadpoint Focus microelectrode targeting system is intended to be used in the operating room by a neurosurgeon, neurologist, or clinical neurophysiologist.	The microTargeting® Guideline 4000 is intended to be used by a neurosurgeon, neurologist or clinical neurophysiologist to accurately position depth electrodes during functional neurosurgical procedures. The Guideline 4000 is intended to be used to accurately position depth electrodes during functional neurosurgical procedures.	Similar
1.2 Clinical Users	The Leadpoint microelectrode targeting system is intended to be used by a neurosurgeon, neurologist, or clinical neurophysiologist.	The Guideline 4000 is intended to be used by a neurosurgeon, neurologist or clinical neurophysiologist.	Similar
1.3 Clinical Environment	The Leadpoint microelectrode targeting system is intended to be used for neurosurgical procedures in the operating room.	The Guideline 4000 is intended to be used during functional neurosurgical procedures.	Similar

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General Design			
2.1 General systems approach	Standard PC based equipment with dedicated hardware peripherals / components.	Standard PC based equipment with dedicated hardware peripherals / components.	Identical
2.2 Configurations	Workstation on cart Portable notebook PC based system	Workstation on cart: Guideline 4000™ Portable notebook PC based system: Guideline 4000 LP+™	Identical
2.3 User input device	Window mouse/keyboard driven graphic interface with dedicated control panel.	Window mouse/keyboard driven graphic interface with dedicated control panel.	Identical
2.4 User output device	Digital color display, loudspeakers and commercial printers.	Digital color display, loudspeakers and commercial printers.	Identical, both devices uses dual loudspeakers for high fidelity audio monitoring.
2.5 Use of standard software platform (Operating System)	Microsoft Windows.	Microsoft Windows.	Identical
2.6 System components	Main Unit including power supply, speakers and control panel Amplifier Macro Stimulator Additional for notebook based system: Notebook PC including monitor, keyboard, and mouse Additional for Workstation: PC, monitor, keyboard, mouse, cart and isolating transformer	Main Unit including power supply, speakers and control panel Amplifier Macro Stimulator Notebook PC including monitor, keyboard, and mouse. Additional for Workstation: PC, monitor, keyboard, mouse, cart and isolating transformer.	Similar
2.7 System – computer interface	USB	USB	Identical
2.8 System power supply	Mains (100-120V~50/60Hz or 200-240V~50/60Hz) through an isolating transformer.	100/120/220/240VAC~50/60Hz. 400VA	Similar
2.9 Display: Size / Resolution	Workstation: 22” / 1680 x 1050 Notebook based system: 15.6” / 1920 x 1080	Notebook based system: 17” / UXGA (1600 x 1200)	Similar
2.10 Safety Isolation	Type BF	Type BF	Identical

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Microeletrode Recording			
3.1 Patient inputs	6 channel amplifier, isolated All active channels continuously displayed.	2 channel amplifier, isolated. Expandable recording channels to a maximum of ten. All active channels continuously displayed.	Standard single sided MER procedures requires simultaneous recording from 1-5 channels. This can be done with both systems.
3.2 Bilateral procedure	Supported with up to 2 x 3 channels	Supported with up to 2 x 5 channels.	Standard MER recordings for bilateral procedures are performed with 2 x 1 channels. This can be performed with both systems
3.5 Input Impedance	>1000Mohm//30pF with electrode cable capacitance reduction	$10^{13}\Omega$ // 0.2 pF AC, 200MΩ DC Differential $10^{13}\Omega$ // 7.0 pF AC, 200MΩ DC Common Mode	Both within the range required for MER. Leadpoint Focus through use of electrode capacitance reduction and the predicate device through unusual high impedances
3.6 Filters	High Pass: 0.01 – 3000 Hz (16 steps) Low Pass: 20 Hz – 13 kHz (12 Steps)	High Pass: Analog: 0 or 240 Hz. Digital: 0 – 1000 Hz Low Pass: Analog: 20 kHz. Digital: 3 - 20 kHz The digital filters are continually adjustable.	Both within the range required for MER. Both systems secure minimal noise: Leadpoint Focus through many steps in the filters and the predicate device via continually adjustable filters.
3.7 Connection Types	1.5mm Touch Proof / DIN socket / Micro D-sub	5 pin DIN socket	Both within the range required for MER.
3.8 Signal acquisition	24 bit analog to digital conversion at 48kHz sample rate	16 bit analog to digital conversion at 48kHz sample rate	Both within the range required for MER.
3.9 Display	Up to six analysis windows.	Up to five analysis windows.	Both within the range required for MER.
3.10 Impedance test	Integrated 220 Hz sine wave, max. 1V / max. 0.1µA	Adjustable 100 Hz - 5 kHz sine wave.	Both within the range required for MER.
3.11 Impedance test range	10 MΩ	Auto ranging 100 kΩ, 1 MΩ or 10 MΩ.	Both within the range required for MER.
3.12 Epoch Recording	Max. 80 s per Epoch	2, 10 or 30 sec	Both within the range required for MER.
3.13 Audio Modes	Raw or clipped sound	Raw or clipped sound	Identical
3.14 Stereotactic systems	Most common	Most common	Identical

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Macro Stimulation			
4.1 Type	Constant Current (CC)	Constant Current (CC)	Identical
4.2 Max output intensity	10 mA	10 mA	Identical
4.3 Voltage Range	0-50 V	0-50 V	Identical
4.4 Intensity resolution	Fine setting: 0.02 mA Coarse setting: 0.1 mA	0.1 mA	Both within the range required for MER
4.5 Stimulus Duration	20 µs – 1 ms (9 steps)	50 µs – 1 ms (8 steps)	Both within the range of required stimulation frequencies (typical 50 µs)
4.6 Repetition Rate	0.1 – 200 Hz (19 steps)	10 - 300Hz (12 steps)	The added range from 0.1 to 10(0) Hz does not add any new risks.
4.7 Stimulus Polarity	Monophasic or biphasic stimulation	Monophasic or biphasic	Identical to the Leadpoint Focus system
4.8 Remote control	Yes, handheld device with controls for stimulation On/Off and intensity	Yes, handheld device with controls for stimulation On/Off and intensity	Identical

Performance data.

Software Test.
The Leadpoint Focus software was tested in accordance with:

FDA guidance: The content of premarket submissions for software contained in medical devices, 11 May 05;

FDA guidance: Off-the-shelf software use in medical devices, 09 Sep 99.

Electrical Safety and Electromagnetic Compatibility (EMC) Test.
The Leadpoint Focus was tested for electrical safety. Test results demonstrated that the Leadpoint Focus complies with:

IEC 60601-1:1988 + A1:1991 + A2:1995.

Electromagnetic Compatibility (EMC) testing was conducted on the Leadpoint Focus according to the applicable standard. Test results indicated that the system complies with the following:

EN/(IEC) 60601-1-2:2007 (3rd edition)

EN/(IEC) 60601-2-40:1998, section 5

EN/(IEC) 61000-3-2:2006+A1+A2

EN/(IEC) 61000-3-3:2008

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Conclusion.

The comparison to the predicate devices demonstrates that the Leadpoint Focus system is safe and effective for its intended use and is substantially equivalent to the predicate devices