# 510(k) Summary
# for the TeleEMG, LLC
# Focus

MAR - 4 2011

*(per 21 CFR 807.92 and http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm)*

## 1. SUBMITTER/510(K) HOLDER

TeleEMG, LLC
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Woburn, MA 01801, USA

Contact Person: Joe F. Jabre, M.D.
Telephone: 617-840-3253
Date Prepared: August 10, 2010

## 2. DEVICE NAME

| | |
|---|---|
| Proprietary Name: | Focus EMG Device |
| Common/Usual Name: | Diagnostic Electromyograph |
| Classification Name: | Diagnostic Electromyograph |
| Product Code: | IKN, JXE |

## 3. PREDICATE DEVICES

- Nemus System, K073415
- Synergy LT, K981405

## 4. DEVICE DESCRIPTION

### Physical Description

The Focus is a 2-channel neurodiagnostic testing system designed to enable reliable recording, display and documentation of electrophysiological information from the human nervous and muscular systems in a clinical environment. The system enables the healthcare provider to perform evoked potentials, nerve conductions and needle EMG studies as an aid in the evaluation of patients with central and peripheral nervous system symptoms.

The device provides functionality for the Electromyography (EMG), Nerve Conduction Studies (NCS), and Evoked Potential (EP) testing for a range of clinical applications and has a fast, intuitive and flexible graphical user interface (GUI) that conforms to a Windows philosophy.

The Focus provides the healthcare professional with:

- A means of adjusting or activating all of the unit's settings and controls.
- Multiple ways in which a user can carry a task, such as from a menu, using the mouse or the keyboard or by double-clicking on an icon.
- Configurable function keys and fields that enable the user to customize the interface to meet their requirements.
- Single-stroke keyboard function keys for key tasks carried out during a patient examination.

In addition to using the GUI, key tasks can be carried out via control switches on the Control Panel, Patient Interface Unit, Amplifiers, and Footswitch.

**Intended Use**

The Focus is intended for use by a healthcare provider to perform nerve conductions and EMG studies as an aid in the evaluation of patients with diseases of muscle and nerves. The machine can also use electrical stimulus or sound stimulus for evoked potentials (EP) studies.

**How the Device Functions**

The device's principle of operation is based on the recording and input of electrical physiological signals (biopotentials) to a computer with the purpose of its analysis. The functional scheme of the device is represented in the figure below:

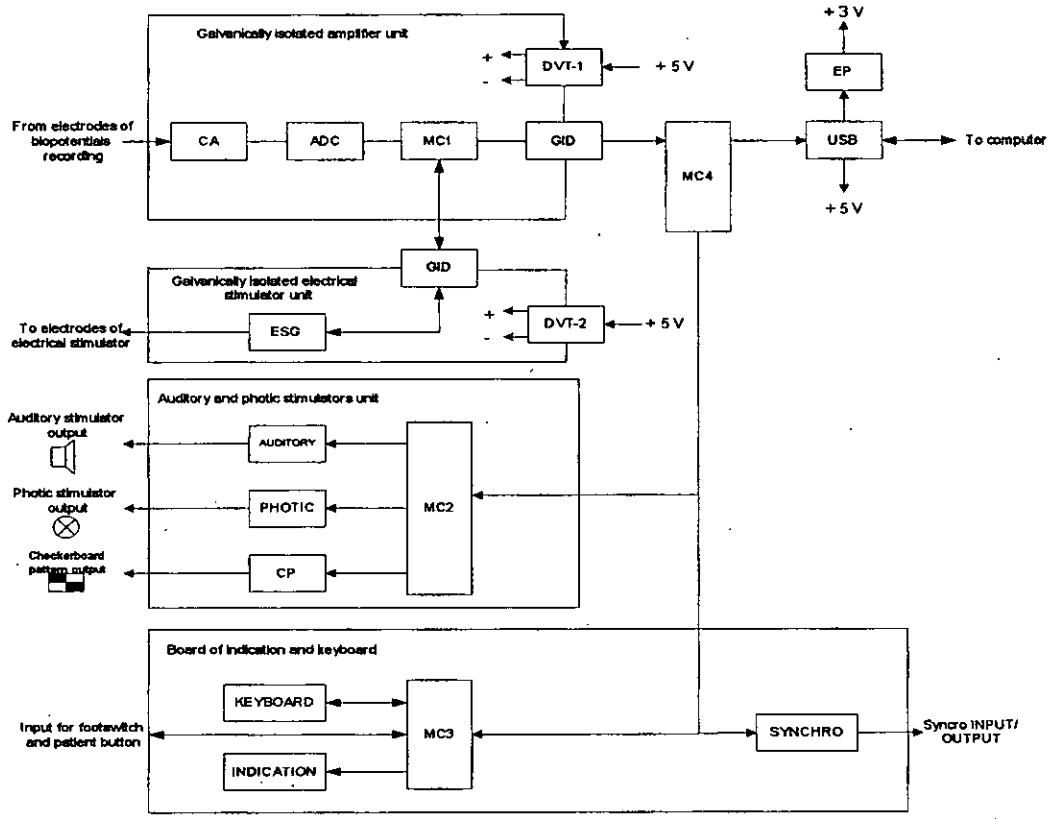



**Figure 5-1. Device Functional Scheme**

EMG biopotentials are amplified by the channels amplifier (CA) and quantized by time and level with the use of the analog-digital converter (ADC) under the control of microcontroller MC1. The commands of the microcontroller MC1 control are transferred from the microcontroller MC4 via the galvanic isolation device (GID), the counts of the input signal are delivered in the reverse direction.

The microcontroller MC1 controls the gain and bandpass of EMG channels amplifiers, is used in the calibration procedures and electrode impedance measurement, and performs the internal diagnostic operations.

The power supply of the amplifier unit is done via the galvanically isolated direct voltage transducer DVT1. The microcontroller MC4 controls the DVT1.

The galvanically isolated electrical stimulator unit includes the electrical stimulus generator (ESG). The microcontroller MC1 specifies the pulse amplitude and duration for the electrical stimulus generator. ESG unit measures the value of the real stimulus current via a patient and transfers it to the microcontroller MC1.

The control of the auditory stimulator, photic stimulator and checkerboard stimulator

is performed via the corresponding auditory, photic, checkerboard pattern generators with the use of the microcontroller MC2 which receives the commands from the computer via MC4.

The microcontroller MC3 performs the displaying of the information to the indicator and entering of information from the buttons, encoders, footswitch and patient button. The given block is located constructively on a separate board.

The microcontroller MC4 also generates the synchro-signal input/output.

The supply unit (SU) transforms the supplying voltage of USB bus to 3.3 V voltage which is required for MC4 operation.

The device operates under control of a PC (IBM PC type) with the mouse, keyboard, laser or jet printer and an installed licensed Windows operational system.

The electronic unit is attached to the USB connector of a computer via the interface cable.

**Significant Physical and Performance Characteristics of the Device, such as Device Design, Material Used, and Physical Properties**

The Focus EMG Device consists of a handheld electronic unit, a stimulator unit with steel electrodes and felt pads, and a footswitch.

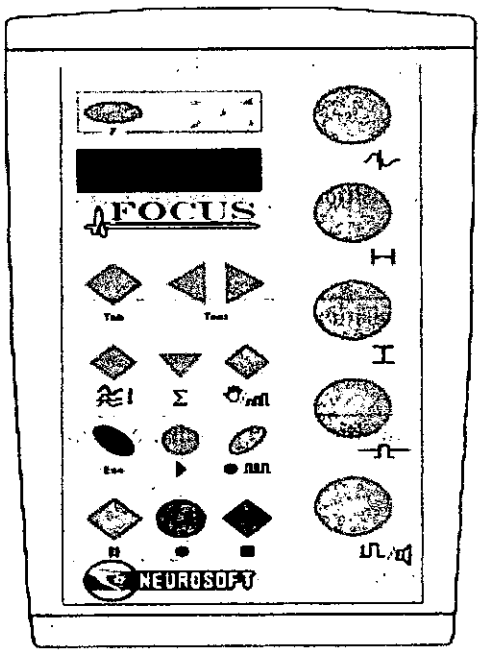



**Figure 5-2. The Electronic Unit**

**Table 5-1. Controls for Handheld Unit**

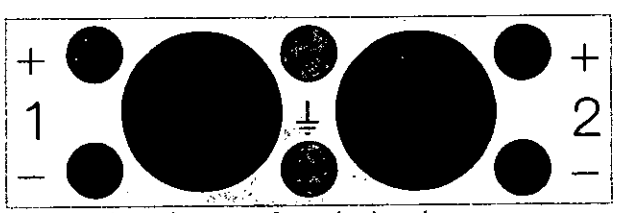
| Button/Encoder | Menu Command/Action |
|---|---|
|  | **Acquisition\|Impedance** |
|  Tab | Key **[Tab]** (intended for switching between input and traces review windows) |
|  Test | **Test\|Next, Test\|Previous** |
|  | **Trace\|Next** |
|  Σ | **Acquisition\|Accumulation/averaging** |

| | |
|---|---|
|  | **Acquisition\|Stimulus protocol (autoincrement)** |
|  Esc | **Acquisition\|Cancel**, same as **[Esc]** key |
|  | **Acquisition\|Monitoring** |
|  | **Acquisition\|Repetitive stimulation** |
|  | **Acquisition\|Pause** |
|  | **Acquisition\|Start acquisition/stimulus** |
|  | **Acquisition\|Stop** |
|  (rotation) | **Trace\|Marker\|Move left and Trace\|Marker\|Move right** |

**Table 5-1. Controls for Handheld Unit (Continued)**

| Button/Encoder | Menu Command/Action |
|---|---|
| (pressing) | Selection of next marker |
| (rotation) | **View\|Sweep\|Increase** and **View\|Sweep\|Decrease** |
| (rotation) | **View\|Sensitivity\|Increase** and **View\|Sensitivity\|Decrease** |
| (rotation) | **Acquisition\|Stimulus\|Increase stimulus duration** and **Acquisition\|Stimulus\|Decrease Stimulus duration** |
| (rotation) | For tests with stimulation: **Acquisition \|Stimulus\|Stimulus increase** and **Acquisition \|Stimulus\|Stimulus decrease**. For tests without stimulation: **Acquisition \|Sound\|Volume up** and **Acquisition \|Sound\|Volume down** |
| (pressing) | For tests without stimulation: **Acquisition\|Sound\|Sound on/off** |

The connectors that attach electrodes for measuring potentials are shown in Figure 5-3.




1+ – touch-proof connector for anode, channel one.
1- – touch-proof connector for cathode, channel one.
2+ – touch-proof connector for anode, channel two.
2- – touch-proof connector for cathode, channel two.
⏚ – Ground connector.

**Figure 5-3. Panel View showing Electrode Connectors**

View of the panel with connectors for the stimulators is given in Figure 5-4.

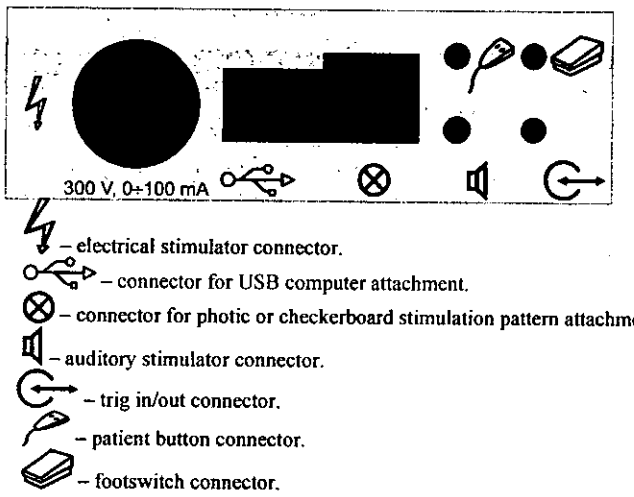



**Figure 5-4. Panel View showing Stimulator Connectors**

The electronic unit measures 92x167x46 mm and weighs .35kg.

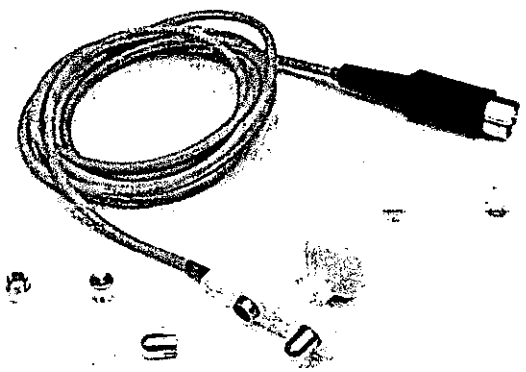


**Figure 5-5. The Stimulator Unit**

The footswitch allows the operator to control the electronic unit. The footswitch measures 103x273x43 mm and weighs 1 kg.

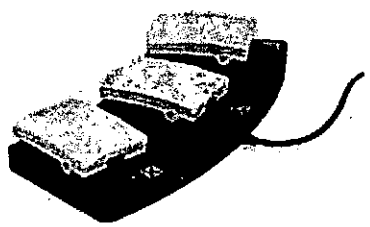


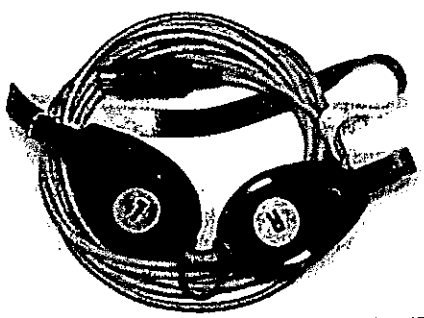
**Figure 5-6. Foot Switch**

The auditory stimulator is used for auditory Evoked Potentials testing. It is connected to the device via the auditory stimulator connection.

| | |
|---|---|
| Multiply Transducer Calibration | Supports up to 6 different transducers with saved calibration values |
| Intensity | 0-126 dBSPL, 0-96dBHL |
| Polarity | -ve, +ve or alternating |
| Stimulation Frequency | 0.05-30 Hz |
| Tone Frequency | 100-8000 Hz |
| Click Duration | 0.1-6 ms |
| Pips/Tone Bursts Intensity | 0-126 dBSPL, 0-96dBHL |
| Presentation | Left / Right / Binaural |
| Loudspeakers | External (computer) |

**Figure 5-6. Foot Switch**

The LED goggles are used in the "Flash Visual EP Test". They are connected via the connector for photic or checkerboard stimulation pattern.



| | |
|---|---|
| Maximum brightness of LED goggles | (1100 ± 110) kd/m$^2$ |
| Flash Duration | 1-500 ms |
| Stimulation Frequency | 0.05-50 Hz |
| Presentation | Left / Right / Both |

**Figure 5-6. Technical Characteristics of the LED Goggles**

## 5. INTENDED USE

The Focus is intended for use by a healthcare provider to perform nerve conductions and EMG studies as an aid in the evaluation of patients with diseases of muscle and nerves. The machine can also use electrical stimulus or sound stimulus for evoked potentials (EP) studies.

## 6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE\PREDICATE DEVICE

### Table 5-2. Side-by-Side Comparison of the Proposed Device with Cited Predicate Devices

| PRODUCT FEATURES | FOCUS EMG DEVICE NEUROSOFT, LTD. PROPOSED | NEMUS SYSTEM EBNEURO S.P.A. K073415 | SYNERGY LT OXFORD INSTRUMENTS K981405 |
|---|---|---|---|
| **Intended Use** | The Focus is intended for use by a healthcare provider to perform nerve conductions and EMG studies as an aid in the evaluation of patients with diseases of muscle and nerves. The machine can also use electrical stimulus or sound stimulus for evoked potentials (EP) studies. | The NEMUS system is intended to monitor, record and display the bioelectric signal produced by the muscles, to stimulate peripheral nerves, and to monitor, record and display the electrical activity produced by nerves to aid the clinician in the diagnosis and prognosis of neuro-muscular diseases (EMG). The device may use electrical stimulus or sound stimulus for use in evoked response measurements (EP). | 2 channel electromyograph which provides facilities for EMG and Evoked Potentials testing for a range of clinical application. Synergy LT is designed to enable reliable recording display and documentation of eleetrophysiological information from the human nervous and muscular system in a clinical environment. |
| Warnings | Items related to off-label use. | Items related to off-label use. | Items related to off-label use. |
| Contraindications | Items related to design and indicated use limitations, such as not for use in the presence of flammable anesthetics or in conjunction with defibrillation equipment. | Items related to design and indicated use limitations, such as not for use in the presence of flammable anesthetics or in conjunction with defibrillation equipment. | Items related to design and indicated use limitations, such as not for use in the presence of flammable anesthetics |
| **Design - General** | | | |
| General system approach | Computer based equipment with dedicated hardware peripherals/components | Computer based equipment with dedicated hardware peripherals/components | Computer based equipment with dedicated hardware peripherals/components |
| User input device | Microsoft Windows mouse/keyboard driven graphic interface. Built-in keyboard | Microsoft Windows mouse keyboard driven graphic interface. Dedicated external keyboard (optional) | Microsoft Windows mouse/keyboard driven graphic interface. |
| User output device | Digital color display Commercial printers | Digital color display Commercial printers | Digital color display Commercial printers |
| Patient inputs | 2 channels preamplifiers, isolated | 2 channels preamplifiers, isolated | 2 channels preamplifiers, isolated |
| Signal acquisition | Analog-to-digital conversion at variable sampling rate | Analog-to-digital conversion at variable sampling rate | Analog-to-digital conversion at variable sampling rate |
| Trigger input (synchronization to external events) | Yes | Yes | Yes |
| Trigger output (synchronization for external devices) | Yes | Yes | Yes |
| Footswitch for hands-free operation | Yes | Yes (Optional) | Yes |
| Use of standard software platform (Operating System) | YES — Microsoft Windows | YES — Microsoft Windows | YES — Microsoft Windows |

## Table 5-2. Side-by-Side Comparison of the Proposed Device with Cited Predicate Devices (Continued)

| PRODUCT FEATURES | FOCUS EMG DEVICE NEUROSOFT, LTD. PROPOSED | NEMUS SYSTEM EBNEURO S.P.A. K073415 | SYNERGY LT OXFORD INSTRUMENTS K981405 |
|---|---|---|---|
| Customization of clinical protocols | Via storage / retrieval of user-defined settings | Via storage / retrieval of user-defined settings | Via storage / retrieval of user-defined settings |
| Application flexibility /expandability | Via software update | Via software update | Via software update |
| Safety Standards | 60601-1-1-2000<br>60601-1-2-2001<br>60601-1-2-40-1998<br>62471-2006 | IEC 60601-1<br>IEC 60601-1-1<br>IEC 60601-2-26<br>IEC 60601-2-40<br>IEC 60601-1-2 | IEC 60601-1 |
| Patient circuitry isolation | Optic/transformer | Optic | Optic |
| System Components | Focus EMG Device<br>USB Cable<br>Footswitch<br>Electrical Stimulator<br>Notebook PC based system | Nemus I Base Unit (Amplifier) Host Computer (PC) Printer (optional) Cart (optional) Dedicated Keyboard (optional) | Headbox (Amplifier)<br>Computer (PC)<br>Cart<br>Printer (optional) |
| Amplifier- Computer interface | USB | LAN Ethernet 100 Mbit | Proprietary |
| System Power Supply | Electronic unit: 5V DC System with Personal Computer: 100-120/200-240 V AC (50-60 Hz) System with Notebook: 100-120/200-240 V AC (50-60 Hz) | From mains (110-240 VAC) trough isolation transformer | From mains (110-240 VAC) |
| Amplifier Power Supply | 5V DC from USB | 15 VDC from medical approved AC/DC converter | Internal power supply |
| Size (H/W/D) mm | Electronic Unit: 90x270x50 mm | Nemus System: 1250/750/850 (complete system, with cart, monitor, arm) | 500/209/321 (cart : 720/640/780 ) |
| Weight (complete system-kg) | Electronic Unit: 0.35<br>System: 3.5 | Nemus System: 90 (complete system, with cart, monitor, arm) | 55 (with cart) |
| **Design - Acquisition** | | | |
| Number of channels | 2 | 2 | 2 |
| CMRR | >100 dB | >100 dB | >110dB |
| Noise | < 0. 6 µVrms. | < 0.3 µVrms (0.1 — 00 Hz) < 20 nV/ √Hz ( 10 Hz — 10 kHz ) | <0.7 µVrms (0.1 Hz — 10 kHz) |
| Input impedance | > 100 MOhm < 25pF | > 1000 MOhm / 8 pF | > 1000 MOhm / 30 pF |
| Low pass filter | (-12dB/octave) 10, 20, 35, 50, 75, 100, 150, 200, 300, 500, 1000, 2000, 3000, 5000, 10000 Hz | 20 Hz — 16 kHz (15 step) | 50 Hz — 16 kHz (10 step) |
| High pass filter | (-6dB/octave) 0.05, 0.1, 0.2, 0.3, 0.5, 1, 2, 3, 5, 10, 20, 30, 50, 100, 200, 300, 500, 1000, 2000, 3000 Hz | 0.01 — 500 Hz (11 step) | DC, 30 — 2000 Hz |
| Notch filter | 50/60 Hz selectable | 50/60 Hz selectable | 50/60 Hz selectable |
| A/D conversion | 16 Bit ADC | 24 bit Sigma-Delta | 16 bit |
| Sampling rate | 200-80000 Hz | 4.194 MHz | 50 kHz |
| Analysis time | 2 ms - 5 min | 5 ms — 10 s | 5 ms — 10s |
| Time base | Single | Single | Single |

**Table 5-2. Side-by-Side Comparison of the Proposed Device with Cited Predicate Devices (Continued)**

| PRODUCT FEATURES | FOCUS EMG DEVICE NEUROSOFT, LTD. PROPOSED | NEMUS SYSTEM EBNEURO S.P.A. K073415 | SYNERGY LT OXFORD INSTRUMENTS K981405 |
|---|---|---|---|
| Trigger mode | Free, Auto, Internal, External | Free, Auto, Internal, External | Auto, Internal, External |
| Signal delay (pre/post) | 0-10 s | 0-5 div | 0 - 9 div |
| Ohmmeter | 0-100 kOhm | 0-100 kOhm (auto full scale) | 0-32 kOhm |
| **Design – Stimulators** | | | |
| Somatosensory (electrical ) Stimulator | Type: constant current<br>N. output 1<br>Max output: 100 mA Pulse width: 0.1 - 5 ms Mode: single, train (50 Hz) | Type: constant current<br>N. output 1<br>Max output: 100 mA Pulse width: 0.05 - 1 ms Mode: single, train | Type: constant current/voltage<br>N. output : 1<br>Max output: 100 mA<br>Pulse width: 0.05-1 ms Mode: single, double, train (200Hz) |
| Audio Stimulator | Output mode: click, tone<br>Sound pressure: 0-126 dB SPL (TDH 39)<br>Phase: condens., raref, alternate<br>Signal frequency: 1008000 Hz<br>Click width: 100-5000 µs<br>Stimulus presen. Left, right, binaural<br>Headset: TDH 39 | Output mode: click, tone<br>Sound pressure: 0-132 dB SPL<br>Phase: condens., raref, alternate<br>Signal frequency: 1258000 Hz<br>Plateau time: 1-200 ms<br>Rise/fall time: 1-100 ms Mask level: -40 ÷ +10 dB (relative)<br>Click width: 1-100 µs Stimulus presen. Left, right, binaural<br>Headset: TDH 39 | Output mode: click, pip, tone<br>Sound pressure: 0-122 dB SPL<br>Phase: condens., raref, alternate<br>Signal frequency: 1258000 Hz<br>Plateau time: 1-999 ms<br>Rise/fall time: 1-255 ms Mask level: -40 ÷ +10 dB (relative)<br>Click width: 0.05 - 1 ms<br>Stimulus presen. Left, right, binaural<br>Headset: TDH 39 |
| **Basic EMG Application Modules** | | | |
| Free run acquisition | Yes | Yes | Yes |
| Nerve conduction study | Yes | Yes | Yes |
| Self triggered acquisition | Yes | Yes | Yes |
| Spontaneous activity | Yes | Yes | Yes |
| Single fiber EMG | Yes | Yes | Yes |
| Motor Unit Analysis | Yes | Yes | Yes |
| F wave analysis | Yes | Yes | Yes |
| H-Reflex analysis | Yes | No | Yes |
| Galvanic Skin Response Also known as Sympathetic Skin Response (SSR) | Yes | No | Yes (Referred to as Sympathetic Skin Response or SSR) |
| **Basic EP Application Modules** | | | |
| Somatosensory EP | Yes | Yes | Yes |
| Auditory EP | Yes | Yes | Yes |
| Visual EP (flash) | Yes | No | Yes |
| P300 EP | Yes | No | Yes |
| Visual EP (pattern) | Yes | No | Yes |

## 7. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

### Performance Testing

Performance evaluation of the features described in the Focus user's manual has been successfully completed utilizing hardware and software tests and validations. Hardware qualification is performed using the following industry standards:

- IEC 60601-1-1:2000 Medical electric equipment Part 1-1: Safety requirements for medical electrical systems
- IEC 60601-1-2:2001 Medical electric equipment Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility –Requirements and tests
- IEC 60601-2-40:1998 Medical electric equipment Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment
- IEC 62471:2006 The TeleEMG Focus EMG Device has met the IEC 62471:2006: Photobiological safety of lamps and lamp systems. According to IEC 62471, our LED goggles luminance is 1,203 cd/m2 that is much less than the admissible level 10,000 cd/m2 specified in clause 4.1 of this standard. That is why it is not required to make additional spectral calculations according to IEC 62471.

The TeleEMG Focus is of a "moderate" level of concern according to the FDA draft software guidance document ("Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"), and meets the requirements set forth in the FDA draft software guidance document for a "moderate" in the level of concern device.

**Biocompatibility Testing**

The only patient contacting surfaces of the Focus EMG device are the stainless steel electrodes and felt pads applied during testing. The electrodes and pads were cleared under the submission of the NC Stat, K060584.

## 8. Summary of Clinical Testing as Basis for Substantial Equivalence

No clinical testing was conducted to support this submission.

## 9. Summary of Other Information

No other information is available.

## 10. Conclusions Drawn from Non-clinical and Clinical Tests

Based on the information and supporting documentation provided in the premarket notification, the Focus EMG Device is substantially equivalent to the cited predicate device. Testing demonstrates that the Focus EMG Device fulfills prospectively defined design and performance specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

TeleEMG, LLC
c/o Joe F. Jabre, M.D.
65 Arlington Road
Woburn, MA 01801

MAR - 4 2011

Re: K102610
Trade/Device Name: Focus EMG
Regulation Number: 21 CFR 890.1375
Regulation Name: Diagnostic Electromyograph
Regulatory Class: Class II
Product Code: IKN, JXE
Dated: January 22, 2011
Received: January 24, 2011

Dear Dr. Jabre:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

for Keosia Alexander

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K102610

Device Name: Focus EMG Device

Indications for Use:

The Focus is intended for use by a healthcare provider to perform nerve conductions and EMG studies as an aid in the evaluation of patients with diseases of muscle and nerves. The machine can also use electrical stimulus or sound stimulus for evoked potentials (EP) studies.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

KRISTEN BOWSHER

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K102610