DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 19, 2015

EB Neuro, S.p.A.
c/o Allison Scott
Navigant Consulting, Inc.
9001 Wesleyan Road, Suite 200
Indianapolis IN 46268

Re: K150220
Trade/Device Name: STM9000 Basic, STM9000 Standard, STM9000 Fast, STM9000 Ultra-Fast
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked Response Electrical Stimulator
Regulatory Class: Class II
Product Code: GWF
Dated: July 16, 2015
Received: July 20, 2015

Dear Ms. Scott,

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 [**SELECT ONE:** Part 801 **[or, for IVDs only]** Parts 801 and 809**]**); 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,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Division 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)*
K150220

Device Name
STM9000 Basic, STM9000 Standard, STM9000 Fast, STM9000 Ultra-Fast

Indications for Use *(Describe)*
The STM9000 is intended for stimulation of peripheral nerves for diagnostic purposes.

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) Summary

I. Submitter Information

EB Neuro, S.p.A.
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Date Prepared: July 17, 2015

807.92(a)(2)

II. Devices

Trade Name: STM9000 Basic, STM9000 Standard, STM9000 Fast, STM9000 Ultra-Fast
Common Name: Evoked Response Electrical Stimulator
Classification Name(s): Evoked Response Electrical Stimulator (21 CFR 882.1870)
Product Code: GWF
Regulatory Class: Class II

III. Predicate & Reference Device(s)

Device	Owner	510(k)	
MagPro, Model R30	Tonica Elektronik A/S	K061645	Predicate
MagPro R30 incl. MagOption, MagPro X100, MagPro X100 incl. MagOption	Tonica Elektronik A/S	K091940	Reference

These devices have not been subject to a design-related recall.

IV. Device Description

The STM 9000 are magnetic stimulators used for magnetic stimulation. Magnetic stimulation is a noninvasive technique for stimulating neural and cortical tissue. Application areas of magnetic stimulation are a subset of the application areas for current stimulation.

The STM 9000 is connected to a magnetic coil which transfers the magnetic stimulation to the tissue. The following coils can be used with the STM 9000 family of magnetic stimulators:

Code	Description
B9621086002	Circular Coil 90 mm
B9621086001	Circular Coil 70 mm
B9621086003	Butterfly Coil 70 mm

B9621086004	Butterfly Coil 70 mm air cooled
B9621086005	Butterfly Coil 80 mm, 120°
B9621086006	Circular Coil 90 mm air cooled

The STM 9000 consists of power electronics to generate the magnetic field in the magnetic coil. The STM 9000 is controlled via a simple user interface, enabling the operator to overview all functions, stimulus sequences, controls, status and measured data. The magnetic pulse is capable of biphasic and monophasic waveforms and the stimulator can stimulate with a frequency up to 100 pulses per second (pps).

V. Intended Use

The STM9000 is intended for stimulation of peripheral nerves for diagnostic purposes.

VI. Comparison of Technological Characteristics

The technological characteristics of STM9000 are similar to those of MagPro R30 and MagPro X100. The devices are magnetic stimulators used for magnetic stimulation as a non-invasive technique for stimulating neural tissue. All devices are capable of single stimulation mode and repetitive stimulation mode.

The subject and predicate devices are connected to magnetic coils which transfer the magnetic stimulation to the tissue. The operator controls the functions and status of the devices through an interface consisting of a graphic LCD, a keyboard and a multifunction knob, integrated in the stimulator. The mechanical, electrical, and magnetic parameters of the coils in this submission are very near to the parameters of the predicate coils.

The main differences between the subject device and predicate are:

- In some configurations, the STM9000 has a lower maximum repetition rate and/or allowable energy level than the predicate configurations

VII. Performance Data

Biocompatibility Testing

The biocompatibility evaluation for the STM9000 was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

The STM9000 coils are considered a surface device contacting intact skin for a duration of less than 24 hours.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the STM9000. The system complies with the IEC 60601-1, IEC 60601-1-4 standards for safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Moderate" level of concern, since a failure or latent flaw in the software could directly result in minor injury to the patient or operator.

VIII. Conclusion

The biocompatibility, electrical safety and EMC, and software verification and validation demonstrate that the STM9000 should perform as well as the predicate device in the specified use conditions.