November 22, 2019

Spes Medica S.r.l.
Giorgio Facco
Regulatory Affairs & Quality Assurance
Via Europa - Zona Industriale
Battipaglia (SA), 84091 Italy

Re: K192603
Trade/Device Name: Spes Medica Subdermal Needle Electrodes
Regulation Number: 21 CFR 882.1350
Regulation Name: Needle Electrode
Regulatory Class: Class II
Product Code: GXZ
Dated: September 18, 2019
Received: September 20, 2019

Dear Giorgio Facco:

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,

Jay Gupta
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192603

Device Name

Spes Medica Subdermal Needle Electrodes

Indications for Use *(Describe)*
Spes Medica Subdermal Needle Electrodes are intended for use with recording, monitoring and stimulation equipment for the purpose of recording of biopotential signals. Examples include: Electromyography (EMG), Electroencephalography (EEG) and Nerve potential signals. The electrodes are sterile and for single patient use only.

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.

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510(k) Summary

Manufacturer's Name:	Spes Medica S.r.l. via Europa (Zona Ind.le), 84091 Battipaglia (SA) – Italy
Official Correspondent:	Giorgio Facco Quality Assurance and Regulatory Affairs
Telephone Number:	0039 0828 614191
Fax Number:	0039 0828 341788
Trade Names:	Spes Medica Subdermal Needle Electrodes
Common or Usual Name:	Subdermal Needle Electrodes
Classification Name:	Needle electrode
Device Class:	Class II
Product Code:	GXZ
Classification Regulation:	882.1350
Predicate Device:	Rhythmlink International Subdermal Needle Electrodes (K022914)
Device Description:	Spes Medica Subdermal Needle Electrodes are monopolar needles intented to use for Electromyography (EMG), Electroencephagraph (EEG) and Nerve potential signals in example and they are intended for use with recording, monitoring and stimulation equipment for the purpose of recording of biopotential signals. The Subdermal Needle Electrodes are used for recording and stimulation (micro stimulation), this stimulation has no therapeutic purpose but has the purpose of activating an electrical response.
Intended Use:	Spes Medica Subdermal Needle Electrodes are intended for use with recording, monitoring and stimulation equipment for the purpose of recording of biopotential signals. Examples include: Electromyography (EMG), Electroencephagraph (EEG) and Nerve potential signals. The electrodes are sterile and for single patient use only.
Technological Comparison:	The electrodes consist of stainless steel needle with a lead wire attached. The lead wires terminate in a safety connector that cannot be connected to an AC power outlet. The characteristics of Spes Medica Subdermal Needle Electrodes are substantially equivalent to the predicate devices. No new questions of safety or effectiveness are raised, Spes Medica Subdermal Needle Electrodes employ the same technological characteristics as the predicate device.
Substantial Equivalence:	Spes Medica Subdermal Needle Electrodes are equivalent to the device cleared under K022914 as is presented below in Table.

It has been shown in this 510(k) submission that the differences between the Spes Medica Subdermal Needle Electrodes and the predicate device Rhythmlink International Subdermal Needle Electrodes do not raise any questions regarding its safety and effectiveness. The Spes Medica Subdermal Needle Electrodes device is substantially equivalent to the predicate device as it has the same intended use and similar technological characteristics as the previously cleared predicate devices. The Spes Medica Subdermal Needle Electrodes, as designed and manufactured is determined to be substantially equivalent to the referenced predicate devices.

Manufacturer	Rhythmlink International LLC	Spes Medica S.r.l.	Discussion Differences
Trade Name	**Rhythmlink International Subdermal Needle Electrodes**	**Spes Medica Subdermal Needle Electrodes**	
510(k) number	**K022914**	**K192603**	
Product Code	**GXZ**	**GXZ**	
Intent for use	Rhythmlink International Subdermal Needle Electrodes are intended for use with recording, monitoring and stimulation equipment for the purpose of recording of biopotential signals. Examples include: Electromyography (EMG), Electroencephagraph (EEG) and Nerve potential signals. The electrodes are sterile and for single patient use only.	Spes Medica Subdermal Needle Electrodes are intended for use with recording, monitoring and stimulation equipment for the purpose of recording of biopotential signals. Examples include: Electromyography (EMG), Electroencephagraph (EEG) and Nerve potential signals. The electrodes are sterile and for single patient use only.	The same of the predicate device
Regulation Name	Needle electrode	Needle electrode	The same of the predicate device
Regulation Number	882.1350	882.1350	The same of the predicate device
Direction for the use	Select appropriate Subdermal Needle Electrode. When introducing Electrode into patient, do not insert up to hub. If needle bends before, during or after insertion, do not straighten or re-insert. Discard and replace with a new Electrode. CAUTION: Needles are sterile only if packaging is unopened. Cleaning & Disinfecting Instructions - This product is single-patient use only. Discard Electrode after use. Other Needle Varieties - Parallel Pairs, Bent and Corkscrew	①Do not use the selected needle if the pouch is damaged; ②Open the pouch and remove needle from sterile pouch; ③Connect the needle with the equipment; ④Remove the needle sheath; ⑤Introduce the needle into the area to be tested. Insert the needle up to hub. ⑥After the use, dispose the needle according to standard protocols or alternatively put the needle in approve biohazard sharps containers. The electrodes are sterile and for single patient only. Other Needle Varieties - Parallel Pairs, Bent and Corkscrew	No significant difference.
Hub Diameter	1.25 mm	1.25 mm	The same of the predicate device
Needle Length	7, 13, 19 and 22 mm	7÷22 mm	The same of the predicate device
Needle Diameter	0.4 mm, 0.6 mm	0.4 mm, 0.6 mm	The same of the predicate device
Connector	DIN 42802	DIN 42802	The same of the predicate device
Leadwire Lengths	1.0, 1.5 and 2.5 m	1.0, 1.5 and 2.5 m	The same of the predicate device
Needle	Stainless Steel	Stainless Steel	The same of the predicate device
Needle Hub	Polyvinylidene Flouride- Polyethelyne (for cork screw)	Polyvinylidene Flouride- Polyethelyne (for cork screw)	The same of the predicate device
Leadwire	Tinned Copper with PVC Jacket Connector	Tinned Copper with PVC Jacket Connector	The same of the predicate device
Protective Cover	PVC, Radio-Opaque Blue	PVC, Radio-Opaque Blue	The same of the predicate device
Single Use	Yes	Yes	The same of the predicate device
Provided to the user sterile	Yes	Yes	The same of the predicate device
Sterilization	Ethylene Oxide	Ethylene Oxide	The same of the predicate device

Manufacturer	Rhythmlink International LLC	Spes Medica S.r.l.	Discussion Differences
Trade Name	**Rhythmlink International Subdermal Needle Electrodes**	**Spes Medica Subdermal Needle Electrodes**	
510(k) number	**K022914**	**K192603**	
Product Code	**GXZ**	**GXZ**	
Shelf life	-	5 years	-
Single Use	Yes	Yes	The same of the predicate device
Pouch (Transparent Layer)	Polyethylene	Polyethylene	The same of the predicate device
Pouch	Tyvek	Medical Paper	No significant difference. Both materials are validated.
Pouch Size	70 x 160 mm	75X200 mm	No significant difference
Box	Paperboard	Paperboard	The same of the predicate device

Performance Testing Summary

Test	Description	Results
Cytotoxicity	These methods are designed to determine the biological response of mammalian cells in vitro using appropriate biological parameters.	The test material showed no reactivity
Skin Irritation	This method describes the procedure for the assessment of medical devices and their constituent materials with regard to their potential to produce irritation and skin sensitization.	The test material showed a negligible irritation response.
Haemolysis test	The aim of the present report is to describe procedure and results obtained for haemolytical potential evaluation test (haemolysis test) of medical device in object.	Subdermal Needles manufactured by purchaser SPES MEDICA does not cause haemolysis.
Skin sensitization	This method describes the procedure for the assessment of medical devices and their constituent materials with regard to their potential to produce irritation and skin sensitization.	On the basis of the results the tested item must be considered not sensitizing.
Systemic toxicity	This method is a biological evaluation to evaluate the systemic toxicity .	On the basis of the results the tested item doesn't cause toxic symptoms and satisfies the requirements of the test.
Pyrogenicity test	The aim of the present report is to describe procedure and results obtained for Pyrogen Test.	On the basis of the results the tested item meets the requirement for the absence of pyrogens
Packaging Validation Protocol (5 years of shelflife)	The accelerated aging process describes a procedures for developing accelerated aging protocols to rapidly determine the effects, if any, due to the passage of time on sterile integrity of the sterile barrier system.	The results stated that the devices and the relative packaging have no substantial alterations after aging process the devices results sterile.

Performance Testing Summary		
Test	**Description**	**Results**
Packaging validation test (Sterility test)	The test is performed in order to determine the charge (expressed in Newton/cm2) necessary to separate the two sides of the seal. This test is performed on both dry and wet material.	All samples met seal strength requirements per ASTM F88
Cable tensile testing	Spes Medica have been tested to get a feedback on the tensile stength of subdermal needles and to understand the limit valuae during pull out the cable.	The results obtained show that for Spes Medica subdermal needles have a very hight strength force during the pull-out test. The average is 40.1 N and this value doesn't affect the needle or the connection part but it is the limit of the cables. The results give to Spes Medica subdermal needles the safety of manufacturing process and the strength of the use.
Impedance test and dieletrich strength	Spes Medica have been tested to get a feedback on the subdermal needles use not only for recording but also for stimulation. The aim is to confirm that the§ devices do not lose their features or worsen their performances after stimulation.	The results obtained show that for Spes Medica subdermal needles, stimulation doesn't affect or reduce the needle and its performance
Electrically Safety - Isolation	Evaluate the isolation of the product in the different part at different voltage 250V, 500V and 1000V.	The results obtained show that for Spes Medica subdermal needles are isolated and are in compliance with requirements for eletrically safety.
Shipment Tests	Understand if: • HANDLING TEST, • VEHICLE STACKING TEST, • LOOSE LOAD VIBRATION TEST, • VEHICLE VIBRATION TEST, • CONCENTRATED IMPACT TEST have a impact on packaging and materials	No damage of the product has been observed
Climatic Tests	Understand if changing temperature and relative humidity (RH) have effects on packaging and materials which may be related to their field performance.	No damage of the product has been observed

We specify that the test articles used in all the tests showed in the *Performance Testing Summary* table are identical to the finished, sterilized proposed in the 510(k) submission per formulation, suppliers, processing, packaging, sterilization (including dose and duration), and geometry and no chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents).

Performance testing - conformance to international standards

The Spes Medica Subdermal Needle Electrodes demonstrated conformance to the following applicable international standards:

- Biocompatibility: ISO 10993-4, 10993-5, 10993-10, and 10993-11
- Sterilization/packaging: ISO 11135-1, 11737-1, and 11737-2; ASTM D4332, ASTM D4169
- Electrical safety:IEC 60601-1: 3rd Ed + CORR 2:2007 + A1:2012 clause 8.5.2.3

Conclusion

All performance testing conducted as outlined above demonstrate that the device met the performance and design specifications.
Based on the results obtained, Spes Medica s.r.l. believes that Spes Medica Subdermal Needle Electrodes are substantially equivalent and performs as well as the the predicate devices (K022914).