DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 21, 2014

Giorgio Facco
Quality Assurance and Regulatory Affairs
Spes Medica s.r.l.
Via Europa – Zona Industriale
Battipaglia (SA), Italy 84091

Re: K133348
Trade/Device Name: IOM Stimulator Probes
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical nerve stimulator/locator
Regulatory Class: II
Product Code: ETN
Dated: October 9, 2014
Received: October 23, 2014

Dear Mr. 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. 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, Ph.D., M.S.
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)*
K133348

Device Name
IOM Stimulator Probes

Indications for Use *(Describe)*
IOM Stimulator Probes are used by the surgeon as the medium to deliver electrical stimulation to tissue during intraoperative neurological monitoring, to identitY nerves and spinal nerve roots and to assess nerve function. 10M Stimulator Probes disposable surgical stimulators are indicated for tissue dissection and stimulation of cranial and peripheral nerves for location and identification during surgery, including spinal nerve roots.

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 of safety and effectiveness

SUBMITTER INFORMATION

A. Company Name: Spes Medica s.r.l.
B. Company Address: Via Europa - Zona industriale
Battipaglia (SA) – Italy 84091
C. Company Phone: +39 010 39 03 43
Company Fax: +39 010 30 72 345
D. Contact Person: Giorgio Facco
Quality Assurance
Spes Medica s.r.l.
e-mail: quality@spesmedica.com

E. Date Summary Prepared: November 04th 2014

DEVICE IDENTIFICATION

A. Device name: IOM Stimulator Probe
B. Trade/Proprietary name: Stim Probe
C. Classification name: Surgical nerve stimulator/locator (21 CFR §874.1820)
D. Product code: ETN

LEGALLY MARKETED DEVICES (PREDICATE DEVICES)

Predicate device	Device Classification Name	510(k) Applicant	510(k) number
RHYTHMLINK Monopolar stimulating instrument	Stimulator Nerve	RHYTHMLINK INTERNATIONAL, LLC	K112435
Drytouch Suction Stimulator probe	Stimulator Nerve	NEUROVISION MEDICAL PRODUCTS, INC.	K110712
XIAN FRIENDSHIP MEDICAL nerve stimulator probes	Stimulator Nerve	XIAN FRIENDSHIP MEDICAL ELECTRONICS CO., LTD.	K112426
SURGICAL STIMULATORS	Stimulator Nerve	TECHNOMED EUROPE	K110422
STIMULUS/DISSECTION INSTRUMENTS, BALL-TIP PROBES	Stimulator Nerve	MEDTRONIC XOMED, INC	K031003

DEVICE DESCRIPTION

IOM Stimulator Probes are used by the surgeon as the medium to deliver electrical stimulation to tissue during intraoperative neurological monitoring, to identify nerves and spinal nerve roots and to assess nerve function. The probes are supplied sterile and are for single use only. The probes are connected to an electrical stimulator using a flexible lead wire(s) and a 'touch-proof' safety connector(s) on the distal end.

All IOM Stimulator Probes are sterilized by Ethylene Oxide and single use only.

The IOM Stimulator Probes are composed by the part in contact with the patient that is medical grade stainless steels, then there is the handle part and cable in biocompatible plastic; finally the cable has a 'touch-proof' safety connectors.

INTENDED USE

IOM Stimulator Probes are used by the surgeon as the medium to deliver electrical stimulation to tissue during intraoperative neurological monitoring, to identify nerves and spinal nerve roots and to assess nerve function. IOM Stimulator Probes disposable surgical stimulators are indicated for tissue dissection and stimulation of cranial and peripheral nerves for location and identification during surgery, including spinal nerve roots.

SUBSTANTIAL EQUIVALENCE

The IOM Stimulator Probes are similar in intended use, design, materials, packaging and other technological characteristics to the predicate devices.

Comparison Chart IOM Stimulator Probes

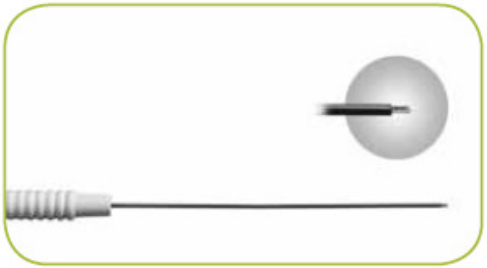
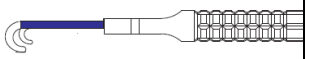
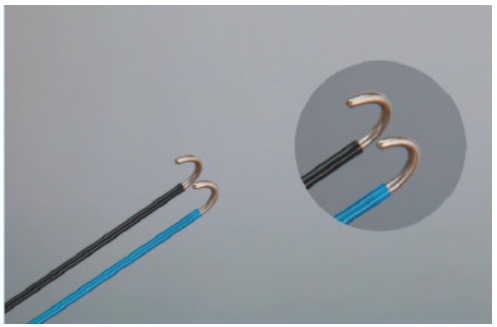
Predicate device	510(k) Applicant	510(k) number	Intent for use	Tip Diam. mm	Shaft Length mm*	Material In contact with patient	Touch proof	Bend Angle	Wire Length cm	Single Use	Steriliz.	Ref. Document
RHYTHMLINK Monopolar stimulating instrument **(Legally Marketed)**	RHYTHMLINK INTERNATIONAL, LLC	K112435	Rhythmlink International Monopolar-Stimulating Instruments Is indicated for stimulation of cranial and peripheral motor nerves for location and identification during surgery; including spinal nerve roots. The Rhythmlink International Monopolar - Stimulating Instruments is sterile and for single use .	3 2.3 1.6 0.75 **Stim Surface mm^3** 3÷44	100 160	Stainless steel	YES	NO	150 250	YES	EtO	004_ Section 09 Rhythmlink

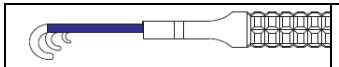
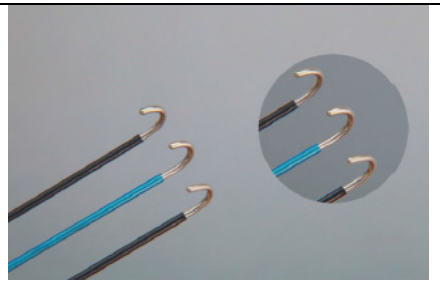
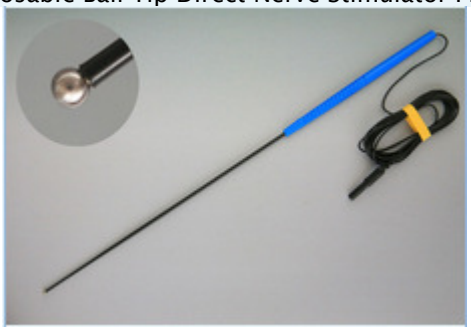
Drytouch Suction Stimulator probe **(Legally Marketed)**	NEUROVISION MEDICAL PRODUCTS, INC.	K110712	The Suction Stimulator Probe is a dedicated manual surgical instrument that allows the surgeon to clear secretions and test surgical tissue with nerve stimulation at the same time and with the same instrument. It is intended for use only **by** a licensed physician and in conjunction with the Neurovision **SE** (Nerveäna) Nerve locator Monitor System.	2 **Stim Surface mm³** 8	130 260	Stainless steel	YES	NO	150	YES	EtO	003_ Section 09 Neurovision
XIAN FRIENDSHIP MEDICAL nerve stimulator probes **(Legally Marketed)**	XIAN FRIENDSHIP MEDICAL ELECTRONICS CO., LTD.	K112426	Xian Friendship Disposable Nerve Stimulator Probes is used to perform localized stimulation of neural tissue and to locate, identify and monitor cranial motor nerves, peripheral nerves and spinal nerve roots during surgery.	2.3 1.3 0.8 1.2 **Stim Surface mm³**	150÷220 80÷150 80÷120 70÷120	Stainless steel	YES	90° (double Hook Probe) 100° (double and triple Hook Probe) 180° (double and triple Hook Probe)	Information not findable	YES	EtO	006_ Section 09 Xian Friendship Medical Electronics

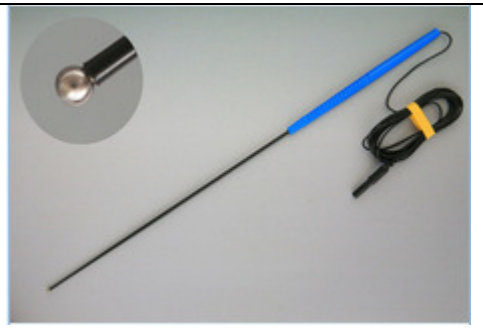
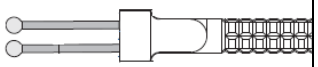
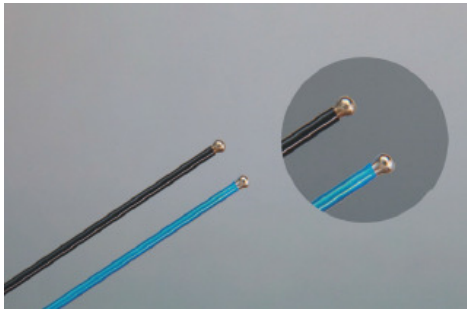
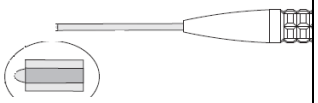
			Xian Friendship Disposable Nerve Stimulator Probes are sterile (EtO), single-patient-use device.	0.5÷100								
SURGICAL STIMULATORS **(Legally Marketed)**	TECHNOMED EUROPE	K110422	The Technomed Europe Kartush disposable surgical stimulators are indicated *for* tissue dissection and stimulation of cranial and peripheral motor nerves for location and identification during surgery, including spinal nerve roots.	0.5 **Stim Surface mm³** 0.125	38,70,100	Stainless steel	YES	NO	Information not findable	YES	EtO	005_ Section 09 Technomed Europe
STIMULUS/DISSECTION INSTRUMENTS, BALL-TIP PROBES **(Legally Marketed)**	MEDTRONIC XOMED, INC	K031003	The Stimulus-Dissection Instruments are indicated for tissue dissection and stimulation of cranial and peripheral motor nerves for location and identification during surgery, including spinal nerve roots.	0.5 1.3 1 2.3 **Stim Surface mm³** 0.125÷12	/	Stainless steel	YES	NO	Information not findable	YES	EtO	002_ Section 09 Medtronic

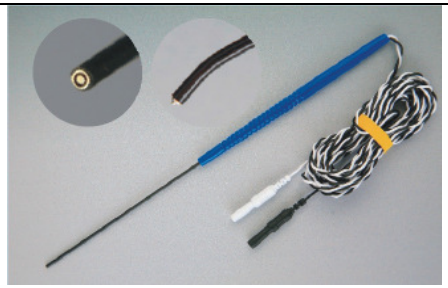
**The information about Handle length in not avaible for any models of any predicates device.*

IOM Stimulator Probes Comparison

Spes Medica Product Name and Drawing	Comparison	Spes Medica Description	Predicate device Photo
Neural stimulator probe insulated monopolar 	The materials is the same, stainless steel, and the probe diameter is in the same range: 1.2 mm for Spes Medica and 1.5 mm for Predicate Device (PD). The shaft length is longer in the PD compared to Spes Medica. The cable length is the same 250 cm (PD has 150 cm too). Both the products as Touch proof connection . Both products are sterilized with EtO .	The probe is a monopolar stimulator probe, It is made by stainless steel AISI 316L, It is insulated with termosrhinkable tube with an insulating thickness of 0,25 mm (KBM100). The part in contact with the patient is the tip of the probe (AISI 316L), the diameter is 1,2 mm and the exposure tip (uncoated surface) is 2 mm . The probe length is 45 mm. The body of the probe is made by coloured polystyrene, It contains the connection (Tin soldering) between probe and lead wire. After the polystyrene there is black thermosrhinkable (18 mm) tube to protect the cable. The cable insulation is made by medical PVC (diameter 1,2 mm). The connector is a coloured T.P. DIN 42802 . The device is EO sterilized and for only single use	Standard Monopolar Stimulating Probe  **Rhythmlink**
Neural stimulator probe bipolar hook 	The materials is the same, stainless steel, and the probe diameter is 1.2 mm for PD and 0.65 mm for Spes Medica. The shaft length is longer in the PD (70÷120mm) compared to Spes Medica (20 mm). Both the products as Touch proof connection . Both products are sterilized with EtO .	The probe is a bipolar hook stimulator probe, It is made by Stainless steel AISI 304, It is PTFE insulated with insulating thikness 0,010-0,015 mm (Duraskin). The part in contact with the patient are the tips of the probe (AISI 304), the diameter is 0,65 mm and the exposure tip (uncoated surface) is 6 mm with a radius R 6 mm. The distance between the two probes is 9 mm (center-center). The probes length are 20 mm. The body of the probe is made by coloured polystyrene, It contains the connections (Tin soldering) between probes and lead wires. After the polystyrene there is black thermosrhinkable (18 mm) tube to protect the cables. The intertwisted cables insulation is made by medical PVC (diameter 1,2 mm). The connector is a coloured T.P. DIN 42802 . The device is EO sterilized and for only single use	Disposable Double Hook Nerve Stimulator Probe-180 degree  **Xian Friendship Medical Electronics**
Neural stimulator probe tripolar hook	The materials is the same, stainless steel, and the probe diameter is 1.2 mm for PD and	The probe is a bipolar hook stimulator probe, It is made by Stainless steel AISI 304, It is PTFE insulated with insulating thikness 0,010-0,015 mm (Duraskin). The part in contact with	Disposable Triple Hook Nerve Stimulator Probe-180 degree

	0.65 mm for Spes Medica. The shaft length is longer in the PD (70÷120mm) compared to Spes Medica (20 mm). Both the products as Touch proof connection . Both products are sterilized with EtO .	the patient are the tips of the probe (AISI 304), the diameter is 0,65 mm and the exposure tip (uncoated surface) is 6mm with a radius R 6 mm. The distance between the three probes is 4,5 mm (center-center each). The probes length are 20 mm. The body of the probe is made by coloured polystyrene, It contains the connections (Tin soldering) between probes and lead wires. After the polystyrene there is black thermosrhinkable (18 mm) tube to protect the cables. The intertwisted cables insulation is made by medical PVC (diameter 1,2 mm). The connector is a coloured T.P. DIN 42802 . The device is EO sterilized and for only single use	 **Xian Friendship Medical Electronics**
Neural stimulator probe monopolar ball 	The materials is the same, stainless steel, and the probe diameter is 3 mm for PD and 2 mm for Spes Medica. The shaft length is longer in the PD (100 mm) compared to Spes Medica (30 mm). The cable length is the same 250 cm (PD has 150 cm too). Both the products as Touch proof connection . Both products are sterilized with EtO .	The probe is a monopolar ball stimulator probe, It is made by stainless steel AISI 316L, It is insulated with termosrhinkable tube with an insulating thickness 0,25 mm (KBM100). The part in contact with the patient is the tip of the probe (AISI 316L), the diameter is 1,7 mm, the ball (exposure tip - uncoated surface) has a diameter of 2 mm . The probe length is 30 mm. The body of the probe is made by coloured polystyrene, It contains the connection (Tin soldering) between probe and lead wire. After the polystyrene there is black thermosrhinkable (18 mm) tube to protect the cable. The cable insulation is made by medical PVC (diameter 1,2 mm). The connector is a coloured T.P. DIN 42802 . The device is EO sterilized and for only single use	Disposable Ball Tip Direct Nerve Stimulator Probe  **Xian Friendship Medical Electronics**
Neural stimulator probe monopolar ball 	The materials is the same, stainless steel, and the probe diameter is 3 mm for PD and 2 mm for Spes Medica. The shaft length is longer in the PD (100 mm) compared to Spes Medica (45 mm). The cable length is the same 250 cm (PD has 150 cm too). Both	The probe is a monopolar ball stimulator probe, It is made by stainless steel AISI 316L, It is insulated with termosrhinkable tube with an insulating thickness 0,25 mm (KBM100). The part in contact with the patient is the tip of the probe (AISI 316L), the diameter is 1,7 mm, the ball (exposure tip - uncoated surface) has a diameter of 2 mm . The probe length is 45 mm. The body of the probe is made by coloured polystyrene, It contains the connection (Tin soldering) between probe and lead wire. After the polystyrene there is black	Disposable Ball Tip Direct Nerve Stimulator Probe

	the products as Touch proof connection . Both products are sterilized with EtO .	thermosrhinkable (18 mm) tube to protect the cable. The cable insulation is made by medical PVC (diameter 1,2 mm). The connector is a coloured T.P. DIN 42802 . The device is EO sterilized and for only single use	 **Xian Friendship Medical Electronics**
Neural stimulator probe bipolar balls 	The materials is the same, stainless steel, and the probe diameter is the same for PD and Spes Medica (2 mm). The shaft length is longer in the PD (70÷120mm) compared to Spes Medica (30 mm). Both the products as Touch proof connection . Both products are sterilized with EtO .	The probe is a bipolar balls stimulator probe, It is made by stainless steel AISI 316L, It is insulated with termosrhinkable tube with an insulating thickness 0,25 mm (KBM100). The part in contact with the patient is the tip of the probe (AISI 316L), the diameter is 1,7 mm, the balls (exposure tips - uncoated surfaces) have a diameter of 2 mm . The distance between the two probes is 6,5 mm (center-center). The probe length is 30 mm. The body of the probe is made by coloured polystyrene, It contains the connection (Tin soldering) between probe and lead wire. After the polystyrene there is black thermosrhinkable (18 mm) tube to protect the cables. The cable insulation is made by medical PVC (diameter 1,2 mm). The connector is a coloured T.P. DIN 42802 . The device is EO sterilized and for only single use	Disposable Double Ball Tip Direct Nerve Stimulator Pro  **Xian Friendship Medical Electronics**
Neural stimulator probe bipolar concentric 	The materials is the same, stainless steel, and the probe diameter is 0.8 mm for PD and 0.32 mm for Spes Medica The shaft length is longer in the PD (80÷150mm) compared to Spes Medica (45	The probe is a bipolar concentric stimulator probe, It is made by stainless steel AISI 304 canula with internal sensor in stainless steel AISI 304, It is insulated with PTFE with an insulating thickness 0,010-0,015 mm (Duraskin). The part in contact with the patient is AISI 304, the diameter of canula is 1,5 mm, the sensor tip has a diameter of 0,32 mm and a length of 0,3 mm. The probe length is 45mm.	Disposable Concentric Direct Nerve Stimulator Probe

	mm). Both the products as Touch proof connection . Both products are sterilized with EtO .	The body of the probe is made by coloured polystyrene, It contains the connection (Tin soldering) between probe and lead wire. After the polystyrene there is black thermosrhinkable (18 mm) tube to protect the cables. The cable insulation is made by medical PVC (diameter 1,2 mm). The connector is a coloured T.P. DIN 42802 . The device is EO sterilized and for only single use	 **Xian Friendship Medical Electronics**
Neural stimulator probe bipolar minifork 	The materials is the same, stainless steel, and the probe diameter is 1.3 mm for PD and 0.65 mm for Spes Medica. Both the products as Touch proof connection . Both products are sterilized with EtO .	The probe is a bipolar minifork stimulator probe, It is made by stainless steel AISI 304, It is insulated with PTFE with an insulating thickness0,010-0,015 mm (Duraskin). The diameter are 0,65 mm, the exposure tips (uncoated surface) have a length of 2 mm . The distance between the two probes is 1,5 mm (center-center). The probe length is 30 mm. The body of the probe is made by coloured polystyrene, It contains the connection (Tin soldering) between probe and lead wire. After the polystyrene there is black thermosrhinkable (18 mm) tube to protect the cables. The cable insulation is made by medical PVC (diameter 1,2 mm). The connector is a coloured T.P. DIN 42802 The device is EO sterilized and for only single use	Kartush Side-by-Side Bipolar Stimulator Probe  **Medtronic**

Neural stimulator probe insulated monopolar		
Specification	**Proposed Spes Medical Probe**	**Rhythmlink – Standard Monopolar Stimulating Probe**
Stimulating Surface Area (mm^2)	7.5 mm^2	4.7 mm^2
Tip Diameter (mm)	1.2 mm	0.75 mm
Shaft Length (mm)	45 mm	100 mm
Lead Length (mm)	250 cm	250 cm and 150 cm
Bend Angle (degrees)	0°	0°
Discussion	The differences between the two devices are shaft length and tip diameter. Shaft is insulated and the length is only an ease of use. The tip diameter is bigger in Spes Medica device, the stimulating area is larger than the PD, this doesn't change in dangerous way current densities. So these two differences not affect the safety and effectiveness as compared to the predicate.	

Neural stimulator probe bipolar hook		
Specification	**Proposed Spes Medical Probe**	**Xian Friendship Medical Electronics – Disposable Double Hook Nerve Stimulator Probe**
Stimulating Surface Area (mm^2)	30.6 mm^2	37.7 mm^2
Tip Diameter (mm)	0.65 mm	1.2 mm
Shaft Length (mm)	20 mm	70-120 mm
Lead Length (mm)	250 cm	Information not avaible
Bend Angle (degrees)	180°	180°
Discussion	The differences between the two devices are shaft length and tip diameter. Shaft is insulated and the length is only an ease of use. The tip diameter is bigger in PD, but the stimulating area doesn't change in dangerous way current densities. So these two differences not affect the safety and effectiveness as compared to the predicate.	

Neural stimulator probe tripolar hook		
Specification	**Proposed Spes Medical Probe**	**Xian Friendship Medical Electronics – Disposable Triple Hook Nerve Stimulator Probe**
Stimulating Surface Area (mm^2)	30.6 mm^2	37.7 mm^2
Tip Diameter (mm)	0.65 mm	1.2 mm
Shaft Length (mm)	20 mm	70-120 mm
Lead Length (mm)	250 cm	Information not avaible
Bend Angle (degrees)	180°	180°
Discussion	The differences between the two devices are shaft length and tip diameter. Shaft is insulated and the length has only an ease of use. The tip diameter is bigger in PD device, stimulating area is smaller than the PD, but the stimulating area doesn't change in dangerous way current densities. So these two differences not affect the safety and effectiveness as compared to the predicate.	

Neural stimulator probe monopolar ball		
Specification	**Proposed Spes Medical Probe**	**Xian Friendship Medical Electronics - Disposable Ball Tip Direct Nerve Stimulator Probe**
Stimulating Surface Area (mm^2)	50.2 mm^2	66 mm^2
Tip Diameter (mm)	2 mm	2.3 mm
Shaft Length (mm)	30 mm and 45 mm	70-150 mm
Lead Length (mm)	250 cm	Information not avaible
Bend Angle (degrees)	0°	0°
Discussion	The differences between the two devices are shaft length and tip diameter. Shaft is insulated and the length has only an ease of use. The tip diameter is bigger in Spes Medica device stimulating area is smaller than the PD, but the stimulating area doesn't change in dangerous way current densities. So these two differences not affect the safety and effectiveness as compared to the predicate	

Neural stimulator probe bipolar balls		
Specification	**Proposed Spes Medical Probe**	**Xian Friendship Medical Electronics – Disposable Double Ball Tip Direct Nerve Stimulator Probe**
Stimulating Surface Area (mm^2)	51 mm^2	51 mm^2
Tip Diameter (mm)	2 mm	2 mm
Shaft Length (mm)	30 mm	70-150 mm
Lead Length (mm)	250 cm	Information not avaible
Bend Angle (degrees)	0°	0°

Neural stimulator probe bipolar concentric		
Specification	**Proposed Spes Medical Probe**	**Xian Friendship Medical Electronics – Disposable Concentric Direct Nerve Stimulator Probe**
Stimulating Surface Area (mm^2)	211 mm^2	201-377 mm^2
Tip Diameter (mm)	1.5 mm	0.8 mm
Shaft Length (mm)	45 mm	80-150 mm
Lead Length (mm)	250 mm	Information not avaible
Bend Angle (degrees)	0°	0°
Discussion	The differences between the two devices are shaft length and tip diameter. Shaft is insulated and the length has only an ease of use. The tip diameter is bigger in Spes Medica device and shaft length is bigger in the PD. At the end the Spes Medica stimulating area is in the range of the PD stimulating area. So these two differences not affect the safety and effectiveness as compared to the predicate.	

Neural stimulator probe bipolar minifork		
Specification	**Proposed Spes Medical Probe**	**Medtronic – Kartush Side-by-Side**

		Bipolar Stimulator Probe
Stimulating Surface Area (mm^2)	9.4 mm^2	8 mm^2
Tip Diameter (mm)	1.5 mm	1.3 mm
Shaft Length (mm)	45 mm	Information not avaible
Lead Length (mm)	250 mm	Information not avaible
Bend Angle (degrees)	0°	0°
Discussion	The differences between the two devices is the tip diameter that is bigger in Spes Medica device. At the end the stimulating area for the two devices is larger than the PD, this doesn't change in dangerous way the current. So this difference not affect the safety and effectiveness as compared to the predicate.	

Nonclinical testing performed
Biocompatibility
Ethylene Oxide Sterilization
Dielectric strength
Packaging
Cleaning Room

CONCLUSION

Comparing these tables and each Spes Medica IOM Stimulator Probes models with PD models we can say that the safety and effectiveness of our device as compared to legally marketed predicate devices. The conclusion of Spes Medica s.r.l. is that the IOM Stimulator Probes are safe and effective as the predicate devices and introduce no new questions concerning safety and effectiveness.