



Food and Drug Administration
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June 3, 2016

Bio Protech, Inc.
% Kevin Han
Manager
Bio Protech Usa, Inc.
2601 Walnut Ave
Tustin, California 92780

Re: K152984

Trade/Device Name: Disposable Concentric Needle Electrodes, Disposable Monopolar Needle Electrodes, Disposable EP Needle Electrodes, Disposable Hypodermic Needle Electrodes

Regulation Number: 21 CFR 890.1385

Regulation Name: Diagnostic electromyograph needle electrode

Regulatory Class: Class II

Product Code: IKT, GXZ

Dated: October 8, 2015

Received: October 9, 2015

Dear Mr. Han:

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" (21 CFR 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 -A

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

Indications for Use

510(k) Number (if known)

K152984

Device Name

Disposable Concentric Needle electrodes, Disposable Hypodermic Needle electrodes, Disposable Monopolar Needle electrodes, Disposable EP Needle electrodes

Indications for Use (Describe)

Disposable Concentric Needle electrodes are sterile electrodes indicated for recording muscle activity for Electromyography (EMG) applications. The electrodes are for single patient use only.

Disposable Monopolar Needle electrodes / EP Needle electrodes are sterile electrodes indicated for recording muscle activity for Electromyography (EMG) and/or Electroencephalography (EEG) applications. The electrodes are for single patient use only.

Disposable Hypodermic Needle electrodes are sterile electrodes indicated for injection of Botulium Toxin while recording muscle activity with Electromyography (EMG) applications. The electrodes are 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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SECTION 10 – 510(k) Summary

SPONSOR:

Bio Protech, Inc.

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Company Contact Person: Kevin Han

Official Correspondent: Judy Burton, Advena USA

Telephone: (972) 243-5105

Date Summary Prepared: April 7, 2016

NEW DEVICE:

Proprietary/Trade Name:

Disposable Concentric Needle electrodes / Disposable Hypodermic Needle electrodes
Disposable Monopolar Needle electrodes / Disposable EP Needle electrodes

Common/Usual Name: Needle Electrodes

Classification Name:

Electrode, Needle, Diagnostic Electromyograph (21 CFR 890.1385, Product Code: IKT)
Electrode, Needle (21 CFR 882.1350, Product Code: GXZ)

Device Class: Class II

PREDICATE DEVICES:

<i>Manufacturer</i>	<i>Trade Name or Model Name</i>	<i>510(k) Number</i>
Bionen S.A.S	Disposable Concentric Needle electrodes Disposable Monopolar Needle electrodes / Subdermal Needle electrodes Disposable Monopolar Needle electrodes	K092973
Technomed Europe	Disposable monopolar and subdermal needle electrodes	K130136
Axon System, Inc.	Subdermal Needle Electrodes, Twisted Pair Needle Electrodes, Corkscrew (spiral) Needle Electrode	K050194

Indications for Use:

Disposable Concentric Needle electrodes are sterile electrodes indicated for recording muscle activity for Electromyography (EMG) applications. The electrodes are for single patient use only.

Disposable Monopolar Needle electrodes / EP Needle electrodes are sterile electrodes indicated for recording muscle activity for Electromyography (EMG) and/or Electroencephalography (EEG) applications. The electrodes are for single patient use only.

Disposable Hypodermic Needle electrodes are sterile electrodes indicated for injection of Botulium Toxin while recording muscle activity with Electromyography (EMG) applications. The electrodes are for single patient use only.

Device Description:

The Bio Protech **Disposable Concentric Needle Electrode** is used for electromyography (EMG) recording for examination of the peripheral neuromuscular system, by registration of the electrical activity from the muscles. Bio Protech Disposable Concentric Needle Electrode consists of a stainless steel cannula and an inner conductor of silver. Between these two conductors there is an insulation layer. The inner conductor is the active measure point and the outer conductor of stainless steel is the reference point. The Stainless steel cannula is coated with a low friction lubricant.

The Bio Protech **Disposable Monopolar / EP Needle Electrode** is intended to be inserted in the subdermal, muscle or nerve tissue for use with recording equipment for the recording of biopotentials signals, EEG or EMG, and proximally connected to electromyography / Electroencephalogram recording equipment. The electrodes consist of a formed stainless steel needle with a lead wire attached. The wire can be directly connected or removable and terminates in a safety connector that cannot be connected to an AC power outlet or and cannot get in touch with possible hazardous voltage.

The Bio Protech **Disposable Hypodermic Needle Electrode** is intended to be inserted in the muscle while recording electromyography activity, and proximally connected to electromyography recording equipment. The electrodes consist of an hypodermic stainless steel needle with an open lumen and a lead wire attached. The wire can be directly connected or removable and terminates in a safety connector that cannot be connected to an AC power outlet or and cannot get in touch with possible hazardous voltage.

Substantial Equivalence Chart:

Compared to the predicate, the subject devices have the same intended use, similar physical and performance characteristics and manufactured using similar process.

Disposable Concentric Needle electrodes & Disposable Hypodermic Needle electrodes

Product characteristics		Needle electrodes	Needle electrodes
Manufacturer		Bio Protech Inc.	BIONEN s.a.s.
510k number		K152984	K092973
Device class		Class II	Class II
Product code		IKT, GXZ	IKT, GXZ
Device type		Needle electrode	Needle electrode
Regulation number		882.1350 / 890.1385	882.1350 / 890.1385
Indications for use	Disposable Concentric needle electrodes	Disposable Concentric Needle electrodes are sterile electrodes indicated for recording muscle activity for Electromyography (EMG) applications. The electrodes are for single patient use only	The BIONEN Disposable Concentric Needle electrodes are sterile electrodes indicated for recording muscle activity for Electromyography (EMG) applications. The electrodes are for single patient use only.
	Disposable Hypodermic Needle electrodes	Disposable Hypodermic Needle electrodes are sterile electrodes indicated for injection of Botulium Toxin while recording muscle activity with Electromyography (EMG) applications. The electrodes are for single patient use only.	The BIONEN Disposable Monopolar Needle electrodes are sterile electrodes indicated for injection of Botulium Toxin while recording muscle activity with Electromyography (EMG) applications. The electrodes are for single patient use only.
Anatomical sites	Disposable Concentric needle electrodes	Subdermal, muscle or nerve tissue	Subdermal, muscle or nerve tissue
	Hypodermic Needle electrodes	Muscle	Muscle
Where used (hospital, home, ambulance , etc)	Disposable Concentric needle electrodes	Electrode preparation and application should be supervised by a qualified healthcare professional.	Electrode preparation and application should be supervised by a qualified healthcare professional.
	Disposable Hypodermic Needle electrodes	Electrode preparation and application should be supervised by a qualified healthcare professional. The specific Botox [®] type to be injected muse be chosen by the physician.	Electrode preparation and application should be supervised by a qualified healthcare professional. The specific Botox [®] type to be injected muse be chosen by the physician.
Design	Disposable Concentric needle electrodes	Ergonomic connector and geometric sharper tip. Color-coded hub	Ergonomic connector and geometric sharper tip. Color-coded hub

Product characteristics		Needle electrodes	Needle electrodes
Manufacturer		Bio Protech Inc.	BIONEN s.a.s.
	Disposable Hypodermic Needle electrodes	Ergonomic connector and geometric sharper tip. The disposable Monopolar Needle electrode consists of a stainless steel cannula electrically insulated with a PTFE coating, except for the lancet point and the inner surface of the tube. The coating is to ensure easy skin penetration and to ensure electrical insulation on the entire cannula, except for the point. A husk fitting together with a wire with connection to an extension cable has been attached to the cannula. This cable will enable the electrical signal to be transferred to a stimulating or recording device.	Ergonomic connector and geometric sharper tip. The disposable Monopolar Needle electrode consists of a stainless steel cannula electrically insulated with a PTFE coating, except for the lancet point and the inner surface of the tube. The coating is to ensure easy skin penetration and to ensure electrical insulation on the entire cannula, except for the point. A husk fitting together with a wire with connection to an extension cable has been attached to the cannula. This cable will enable the electrical signal to be transferred to a stimulating or recording device.
Performance	Disposable Concentric needle electrodes	Tested for penetration and friction force and electrical properties (according to DIN 13097). Ageing tests are performed to verify and ensure the functionality during the shelf life of the product.	Tested for penetration and friction force and electrical properties (according to DIN 13097). Ageing tests are performed to verify and ensure the functionality during the shelf life of the product.
	Disposable Hypodermic Needle electrodes	Sharpening; Camera visual examination with special attention to bevel and burrs; Electrical continuity and isolation of all poles;	Sharpening; Camera visual examination with special attention to bevel and burrs; Electrical continuity and isolation of all poles;
Standards met		IEC 60601-1 ISO 10993-1 ISO 10993-10 ISO 10993-5 ISO 11137 ISO 11607-1(compliable with UNI EN 11607-1) ASTM F88(compliable with UNI EN 868-5)	IEC 60601-1 ISO 10993-1 ISO 10993-10 ISO 10993-5 ISO 11137 UNI EN 11607-1 UNI EN 868-5
Materials	Disposable Concentric Needle electrode	Stainless Steel cannula, silver, ABS Hub, Epoxy Insulator, PELD Plastic protector, Stainless steel / gold plated connection	Stainless Steel cannula, Platinum / Stainless Steel sensor, Polyethylene(PE) Hub, Epoxy Insulator, PELD Plastic protector, Stainless steel / gold plated connection
	Disposable Hypodermic Needle electrode	Stainless steel cannula, ABS Hub, PELD Plastic protector, stainless steel/gold plated connection, lead wire	Stainless steel cannula, polyethylene (PE) Hub, PELD Plastic protector, stainless steel/gold plated connection, lead wire
Dimensions	Disposable Concentric Needle electrode	Diameter = 0.30/0.45/0.36/0.65mm L=25-30-38-50-75mm	Diameter = 0.45/0.35mm L=25-30-35-40-45-50-65mm

Product characteristics		Needle electrodes	Needle electrodes
Manufacturer		Bio Protech Inc.	BIONEN s.a.s.
	Disposable Hypodermic Needle electrode	Diameter = 0.30/0.40/0.45/0.65mm L=25-37-40-50-75mm	Diameter = 0.50mm L=20-30-40-50-60mm
Recording area	Disposable Concentric Needle electrode	0.02-0.07mm ²	0.02-0.07mm ²
Connector cable	Disposable Concentric Needle electrode	DIN 5 poles	DIN 5 poles
Biocompatibility		Selection of materials, which demonstrate appropriate levels of biocompatibility. Tests on basis of ISO 10993-1	Selection of materials, which demonstrate appropriate levels of biocompatibility. Tests on basis of ISO 10993-1
Compatibility with the environment and other devices		Compatibility is achieved through the connecting cable to EMG/EEG machines or similar physiological recording devices.	Compatibility is achieved through the connecting cable to EMG/EEG machines or similar physiological recording devices.
Sterility		EO sterilization	Gamma irradiation
Shelf life		3 years	60 months
Electrical safety		The "touch-proof" safety connector is specifically designed so that it cannot be plugged into AC power outlet and cannot get in touch with possible hazardous voltage	The "touch-proof" safety connector is specifically designed so that it cannot be plugged into AC power outlet and cannot get in touch with possible hazardous voltage
Mechanical safety		Packaged needle covered with a needle cover.	Packaged needle covered with a needle cover.
Chemical safety		Not applicable	Not applicable
Thermal safety		Not applicable	Not applicable
Radiation safety		Not applicable	Not applicable

Disposable Monopolar Needle electrodes / EP Needle electrodes

Product characteristics	Disposable Monopolar Needle electrodes / EP Needle electrodes (Corkscrew Needle electrode) (spiral)	Disposable monopolar and subdermal needle electrodes	Subdermal Needle Electrodes, Twisted Pair Needle Electrodes Corkscrew Needle Electrode (spiral)
Manufacturer	Bio Protech Inc.	Technomed Europe	Axon System, Inc.
510k number	K152984	K130136	K050194
Device class	Class II	Class II	Class II
Product code	IKT, GXZ	IKT, GXZ	GXZ
Device type	Needle electrode	Disposable monopolar needle electrode, disposable subdermal needle electrode	Subdermal Needle electrode
Regulation number	882.1350 / 890.1385	882.1350 / 890.1385	882.1350

Product characteristics	Disposable Monopolar Needle electrodes / EP Needle electrodes (Corkscrew Needle electrode) (spiral)	Disposable monopolar and subdermal needle electrodes	Subdermal Needle Electrodes, Twisted Pair Needle Electrodes Corkscrew (spiral) Needle Electrode
Manufacturer	Bio Protech Inc.	Technomed Europe	Axon System, Inc.
Indications for use	Disposable Monopolar Needle electrodes / EP Needle electrodes are sterile electrodes indicated for recording muscle activity for Electromyography (EMG) and/or Electroencephalography (EEG) applications. The electrodes are for single patient use only.	Disposable Monopolar and Subdermal Needles are intended for use with recording, monitoring and stimulation/recording equipment for the stimulation/recording of biopotential signals including electromyography(EMG) and nerve potential signals	Axon System/s Subdermal Needle Electrodes are intended for use with recording, monitoring and stimulation/recording equipment for the recording of biopotential signals including electroencephalograph(EEG), electromyography(EMG) and nerve potential signals and for stimulation during the intraoperative diagnosis of acute dysfunction in corticospinal axonal conduction
Anatomical sites	Subdermal, muscle or nerve tissue	Peripheral nerves and muscle	Subdermal
Where used (hospital, home, ambulance, etc)	Electrode preparation and application should be supervised by a qualified healthcare professional.	Hospital	Use by a licensed physician or technologist under the supervision of a physician.
Design	Ergonomic connector and geometric sharper tip. Color-coded hub	Unknown Tip Geometry: Front bevel and pencil tip	Unknown
Performance	Sharpening; Camera visual examination with special attention to bevel and burrs; Electrical continuity and isolation of all poles;	Unknown	Unknown
Standards met	IEC 60601-1 ISO 10993-1 ISO 10993-10 ISO 10993-5 ISO 11137 ISO 11607-1(compliable with UNI EN 11607-1) ASTM F88(compliable with UNI EN 868-5)	Unknown	Unknown
Materials	Stainless Steel	Stainless Steel, Pt/Ir	Stainless steel needle
Dimensions	Diameter = 0.36/0.45mm L=25-37-50-75m Diameter = 0.40mm L=12mm	Diameter = 0.30~0.65mm L=25~75mm (monopolar) 7~20mm(subdermal) 23mm(corkscrew) Diameter = 0.40mm L=12mm	Diameter = 0.40mm

Product characteristics	Disposable Monopolar Needle electrodes / EP Needle electrodes (Corkscrew (spiral) Needle electrode)	Disposable monopolar and subdermal needle electrodes	Subdermal Electrodes, Twisted Pair Electrodes Corkscrew Needle Electrode (spiral)
Manufacturer	Bio Protech Inc.	Technomed Europe	Axon System, Inc.
Biocompatibility	Selection of materials, which demonstrate appropriate levels of biocompatibility. Tests on basis of ISO 10993-1	No further biocompatibility testing was determined to be necessary.	Unknown
Compatibility with the environment and other devices	Compatibility is achieved through the connecting cable to EMG/EEG machines or similar physiological recording devices.	Unknown	Unknown
Sterility	EO sterilization	EO sterilization	Unknown
Shelf life	3 years	Unknown	Unknown
Electrical safety	The "touch-proof" safety connector is specifically designed so that is cannot the plugged into AC power outlet and cannot get in touch with possible hazardous voltage	Electrical insulation on all surfaces not all surfaces not intended to provide electrical contact with the patient and connection DIN 42802 1.5mm touch proof	The DIN 42802 safety connector is specifically designed so that is cannot the plugged into AC power outlet
Mechanical safety	Packaged needle covered with a needle cover.	Unknown	Packaged needle covered with a needle cover.
Chemical safety	Not applicable	Not applicable	Not applicable
Thermal safety	Not applicable	Not applicable	Not applicable
Radiation safety	Not applicable	Not applicable	Not applicable

Technological Characteristics

Disposable Concentric Needle Electrode consists of a stainless steel cannula and an inner conductor that can be of Silver. Between these two conductors there is an insulation layer. The inner conductor is the active measure point and the outer conductor of stainless steel is the reference point. The Electrode has a plastic (ABS) ergonomic hub.

Disposable Monopolar Needle Electrode / EP Needle Electrode consist of a formed stainless steel needle with a lead wire attached and Disposable Monopolar Needle Electrode (Non-wired model) can be connected with detachable cable for use. The lead wire terminates in a safety connector that cannot be connected to an AC power outlet.

Disposable Hypodermic Needle Electrode consists of a hypodermic stainless steel needle with an open lumen and a lead wire attached. The Stainless steel cannula is coated by Teflon (PTFE) for low friction. The lead wire terminates in a safety connector that cannot be connected in a AC power outlet.

Sterility and Shelf Life Testing:

The typical samples passed accelerated aging testing conducted by KTR (Korea Testing and Research Institute) according to ASTM F 1980, "Accelerated aging of sterile barrier systems for medical devices"; FDA recognition number 14-355. The test results indicate the products conducted reliability of shelf-life of 3 years.

The method of sterilization for Needle Electrodes is EO sterilization.

Accelerated aging tests were conducted according to ASTM F 1980, "Accelerated aging of sterile barrier systems for medical devices." The test results indicate the Needle Electrodes has a shelf-life of 3 years.

The Needle Electrodes passed EO residual testing performed according to ISO 10993-7: 2008 Ethylene Oxide Residuals.

Biocompatibility Testing:

Biocompatibility evaluations of manufactured and sterilized Bio Protech electrodes were performed for cytotoxicity (ISO MEM elution), intracutaneous reactivity, Guinea pig maximization sensitization, acute systemic toxicity, material-mediated pyrogenicity (rabbit), and hemolysis.

Safety and Effectiveness Testing:Performance Testing Bench:

Needle electrodes of Bio Protech are tested for verifying the substantial equivalence of penetration and friction force according to DIN 13097. Bio Protech Needle electrodes were tested for comparing the penetration and friction force performance of the Bio Protech Needle electrodes against the predicate devices.

The result of testing shows that the electrodes are as safe, effective and perform at least as the legally marketed device.

Performance Testing Animal: Animal testing is not required for this device.

Performance Testing Clinical: Clinical testing is not required for this device.

Conclusion:

Needle electrodes of Bio Protech are substantially equivalent to the predicate devices in indications for use, materials and design. The Needle electrodes can be considered the adequate needle electrodes in regard to safety and effectiveness.