K092973

BIONEN
medical devices

1 510(k) Summary or 510(k) Statement

OCT 7 2010

Bionen s.a.s
Via P. Petrocchi, 42/1
Florence, Italy 50127
P: 39 055 4265945
F: 39 055 412188

Contact: Allison Scott, RAC

Date: September 21, 2010

Trade Name: Disposable Concentric Needle Electrode
Disposable Monopolar/Subdermal Needle Electrode
Disposable Monopolar Needle Electrode

Common Name: Needle Electrodes

Classification Name: EMG Diagnostic Needle (21 CFR 890.1385, Product Code IKT)
Needle Electrode (21 CFR 882.1350, Product Code GXZ)

Predicate Devices:

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
Concentric Needle Electrode		
K071186	Neuroline, Disposable Concentric needle electrode	Ambu A/S
K931966	Needle electrode EMG	Alpine Biomed (ex Dantec)
Monopolar/Subdermal Needle Electrode		
K050194	Subdermal Needle Electrodes, Twisted Pair Needle Electrodes, Corkscrew (spiral) Needle Electrode	Axon Systems, Inc.
Disposable Monopolar Needle Electrode		
K091410	Myobot Needles	Spes Medica
K062437	Disposable Hypodermic Needle Electrode	Technomed Europe

Device Description:

The BIONEN **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.

BIONEN Disposable Concentric Needle Electrode consists of a stainless steel cannula and an inner conductor of stainless steel or platinum. 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 BIONEN **Disposable Monopolar/Subdermal 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 BIONEN **Disposable Monopolar 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.

Indications for Use:

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

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

The BIONEN **Disposable Monopolar Needle electrodes** are sterile electrodes indicated for injection of Botulinum Toxin while recording muscle activity with Electroymyography (EMG) applications. The electrodes are for single patient use only.

Technological Characteristics:

BIONEN **Disposable Concentric Needle Electrode** consists of a stainless steel cannula and an inner conductor that can be of stainless steel or platinum. 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 Electrode has a plastic (NYLON) ergonomic hub.

BIONEN **Disposable Monopolar/Subdermal Needle Electrode** consists of a formed stainless steel needle with a lead wire attached. The lead wire terminates in a safety connector that cannot be connected to an AC power outlet.

BIONEN **Disposable Monopolar Needle Electrode** consists of an hypodermic stainless steel needle with an open lumen and a lead wire attached. The lead wire terminates in a safety connector that cannot be connected in a AC power outlet.

Substantial Equivalence Discussion:

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

Concentric Needle Electrodes

product characteristics	**Needle electrodes**	Neuroline, Disposable Concentric needle electrode	DCN™ Disposable Concentric Needle Electrodes
manufacturer	**BIONEN s.a.s.**	**Ambu A/S**	**Alpine Biomed (ex Dantec)**
510K number	K092973	K071186	K931966
Device class	Class II	Class II	Class II
Product code	IKT	IKT	IKT
Device type	Needle electrode	Disposable Concentric needle electrode	Electrode, needle, diagnostic electromyograph
Regulation number	882.1350 890.1385	890.1385	890.1385
indications for use	The BIONEN Disposable Concentric Needle electrodes are sterile electrodes indicated for recording muscle activity for Electroymyography (EMG) applications. The electrodes are for single patient use only.	The Neuroline, Disposable Concentric needle electrodes are made for muscle activity recording for Electromyography (EMG) applications. The electrodes are for single patient use only.	Alpine Biomed Disposable Needle Electrodes cannot be re-sterilized and are for single patient use only. Do not reuse but discard used needle electrodes in a properly marked medical biohazard sharps container.
anatomical sites	subdermal, muscle or nerve tissue	muscles	subdermal, muscle or nerve tissue
where used (hospital, home, ambulance, etc)	Electrode preparation and application should be supervised by a qualified healthcare professional.	same	same

product characteristics	**Needle electrodes**	Neuroline, Disposable Concentric needle electrode	DCN™ Disposable Concentric Needle Electrodes
manufacturer	**BIONEN s.a.s.**	**Ambu A/S**	**Alpine Biomed (ex Dantec)**
design	Ergonomic connector and geometric sharper tip. Color–coded hub	Ergonomic and Color–coded hub	Pre-sterilized DCN™ Electrodes have true ergonomic design and are always sharp. Each needle has a matching colour-coded hub and package for easy identification and reordering. The hub has a raised bevel indicator, so you always know the direction of the recording surface. The needle features a coaxial hub that allows you to easily connect the needles into the HUSH™ electrode cables without orientation. A wiping contact is used inside the hub to optimize the connection throughout the life of the cable and reduce oxide build-up. The cable can withstand a 50 lbs pull test, so it is made to last.
performance	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.	Unknown
standards met	IEC 60601-1 ISO 10993-1 ISO 10993-10 ISO 10993-5 ISO 11137 UNI EN 11607-1 UNI EN 868-5	unknown	Unknown

product characteristics	**Needle electrodes**	Neuroline, Disposable Concentric needle electrode	DCN™ Disposable Concentric Needle Electrodes
manufacturer	**BIONEN s.a.s.**	**Ambu A/S**	**Alpine Biomed (ex Dantec)**
materials	Stainless Steel cannula, Platinum / Stainless Steel sensor, Polyethylene (PE) Hub, Epoxy Insulator, PELD Plastic protector, Stainless steel/gold plated connection	Stainless steel cannula, Silver sensor, ABS Hub, Epoxy Insulator, Polyethylene (PE) Plastic protector, brass/gold plated connection	Stainless Steel cannula, Platinum sensor
Dimensions	Diameter = 0.45/0.35 mm L=25-30-35-40-45-50-65mm	Diameter = 0.45/0.35 mm L=25-30-38-50-75mm	Diameter = 0.30/0.46/0.64 mm L=25-37-50-75mm
Recording area	0,02 – 0,07mm^2	0,02 – 0,07mm^2	0.019 – 0.07mm^2
Connector cable	Din 5 poles	Din 5 poles	Din 5 poles
biocompatibility	selection of materials, which demonstrate appropriate levels of biocompatibility. Tests on the basis of ISO 10993-1	selection of materials, which demonstrate appropriate levels of biocompatibility. Tests on the basis of ISO 10993-1	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	Gamma irradiation	E-beam	E-Beam.
Shelf life	60 months	36 months	36 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	unknown	Unknown
mechanical safety	Packaged needle covered with a needle cover.	Packaged needle covered with a needle cover.	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

Monopolar/Subdermal Needle Electrodes

product characteristics	**Needle electrodes**	Subdermial Needle Electrodes, Twisted Pair Needle Electrodes, Corkscrew (spiral) Needle Electrode
manufacturer	**BIONEN s.a.s.**	**Axon Systems, Inc.**
510K number	K092973	K050194
Device class	Class II	Class II
Product code	GXZ	GXZ
Device type	Monopolar/Subdermal Needle electrode	Subdermal Needle electrode
Regulation number	882.1350	882.1350
indications for use	The BIONEN Disposable Monopolar/Subdermal Needle electrodes are sterile electrodes indicated for recording muscle activity for Electroymyography (EMG) and/or Electroencephalography (EEG) applications. The electrodes are for single patient use only.	Axon Systems' Subdermal Needle Electrodes are intended for use with recording, monitoring and stimulation/recording equipment for the recording of biopotential signals including electroencephalograph (EEG), electromyograph (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	subdermal
where used (hospital, home, ambulance, etc)	Electrode preparation and application should be supervised by a qualified healthcare professional.	Use by a licensed physician or technologist under the supervision of a physician.
design	Ergonomic connector and geometric sharper tip. Color–coded hub	Unknown
performance	Sharpening; Camera visual examination with special attention to bevel and burrs; Electrical continuity and isolation of all poles;	Unknown
standards met	IEC 60601-1 ISO 10993-1 ISO 10993-10 ISO 10993-5 ISO 11137 UNI EN 11607-1 UNI EN 868-5	unknown
materials	Stainless Steel / platinum needle	Stainless steel needle
Dimensions	Diameter=0,35mm L=15-20mm	Diameter=0,4mm
biocompatibility	selection of materials, which demonstrate appropriate levels of biocompatibility. Tests on the basis of ISO 10993-1	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
sterility	Gamma irradiation	unknown

product characteristics	Needle electrodes	Subdermial Needle Electrodes, Twisted Pair Needle Electrodes, Corkscrew (spiral) Needle Electrode
manufacturer	BIONEN s.a.s.	Axon Systems, Inc.
Shelf life	60 months	unknown
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 DIN 42802 "touch-proof' safety connector is specifically designed so that it cannot be plugged into AC power outlet
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 electrode

product characteristics	Disposable Monopolar Needle electrode	Myobot Needle	Disposable Hypodermic Needle Electrode
manufacturer	BIONEN s.a.s.	Spes Medica	Technomed Europe
510K number	K092973	K091410	K062437
Device class	Class II	Class II	Class II
Product code	IKT	IKT	IKT
Device type	Needle electrode	Needle electrode	Needle electrode
Regulation number	890.1385	890.1385	890.1385
indications for use	The BIONEN Disposable Monopolar Needle electrodes are sterile electrodes indicated for injection of Botulinum Toxin while recording muscle activity with Electroymyography (EMG) applications. The electrodes are for single patient use only.	Recording muscle activity for Electromyography (EMG) applications. For single patient use only. The disposable hypodermic needle is inteded to be used for injection of the Botulinum Toxin into a muscle, while recording electromyography activity. The electrode has an open lumen and is designed for muscle stimulation, motor unit action, potential recording and Botulinum Toxin injection.	The disposable hypodermic EMG needle electrode is used for muscle stimulation, motor unit action potential recording and drug delivery. The motor nerves are monitored by detecting EMG activity in the muscles they innervate. The drug used should be Botox Botilium Toxin type A. Note: Technomed Europe does not supply any drugs with the Disposable hypodermic EMG needle electrodes nor does Technomed Europe offer for sale any form of drugs.
anatomical sites	muscle	muscle	muscle

product characteristics	Disposable Monopolar Needle electrode	Myobot Needle	Disposable Hypodermic Needle Electrode
manufacturer	BIONEN s.a.s.	Spes Medica	Technomed Europe
where used (hospital, home, ambulance, etc)	Electrode preparation and application should be supervised by a qualified healthcare professional. The specific Botox® type to be injected must be chosen by the physician.	unknown	unknown
design	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	unknown	The disposable hypodermic EMG 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	Sharpening; Camera visual examination with special attention to bevel and burrs; Electrical continuity	unknown	unknown
standards met	IEC 60601-1 ISO 10993-1 ISO 10993-10 ISO 10993-5 ISO 11137 UNI EN 11607-1 UNI EN 868-5	unknown	unknown
materials	Stainless Steel cannula, Polyethylene (PE) Hub, PELD Plastic protector, Stainless steel/gold plated connection, lead wire	Stainless Steel cannula	Stainless steel cannula, PTFE coating, lead wire

product characteristics	Disposable Monopolar Needle electrode	Myobot Needle	Disposable Hypodermic Needle Electrode
manufacturer	**BIONEN s.a.s.**	**Spes Medica**	**Technomed Europe**
Dimensions	Diameter=0,50mm L=20-30-40-50-60mm	Diameter=0,30-0,40-0,45-0,50-0,55-0,70mm L=25-37-50-75mm	Diameter=0,30-0,40-0,45-0,50mm L=25-37-50-75mm
biocompatibility	Tests on the basis of ISO 10993-1 table 1 made on the Concentric needle electrode as the worse case are considered valid and extensible to this kind of device.	unknown	unknown
compatibility with the environment and other devices	Compatibility is achieved through the connecting cable to EMG machines or similar physiological recording devices.	unknown	unknown
sterility	Gamma irradiation	unknown	unknown
Shelf life	60 months	unknown	unknown
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	unknown	unknown
mechanical safety	Packaged needle covered with a needle cover.	Packaged needle covered with a needle cover.	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

Discussion of Nonclinical Tests Submitted:

The non-clinical tests performed are laboratory tests to verify the functionality of the BIONEN Needle Electrodes. The following standards were applied during testing:

IEC 60601-1:2005	UNI EN 868-5:2002
UNI EN ISO 10993-1	UNI EN 556-1 :2002
UNI EN ISO 10993-10	ASTM F1980-07
UNI EN ISO 10993-5	ASTM F2054-00
UNI EN ISO 11137-1	DIN 58953-6
UNI EN ISO 11137-2	ASTM F1929-98
UNI EN ISO 11137-3	ASTM F1886-98
DIN 13097:2009	ISO 11607-1

The Concentric Needle Electrode is tested for penetration and friction force according to DIN 13097. The result of testing indicates that the electrodes are as safe, as effective, and perform at least as safely and effectively as the legally marketed device.

Ageing tests was performed to verify and ensure the functionality during the shelf life of the product.

Quality control tests are performed on every lot:

- Needle sharpening: visual examination with a microscope camera
- Bevel and burrs: visual examination with a microscope camera
- Needle continuity: automated process (100% control)
- Needle pole isolation: automated process (100% control)

The Monopolar/Subdermal needle electrode is tested on 10% of every lot:

- Needle sharpening: visual examination under microscope
- Bevel and burrs: visual examination under microscope
- Needle continuity: audible ohmmeter

Bioburden tests and Dose Audit are performed every 9 months by a third laboratory to verify the microbic load on a sample of the specific batch manufactured.

BIONEN has determined its reference value at 100UFC and Bioburden results are always extensively under this value.

The biological safety of the BIONEN Concentric Needle Electrode has been assured through the selection of materials, which demonstrate appropriate levels of biocompatibility.

Some tests were selected for the Biological evaluation of Medical Device on the basis of ISO 10993-10 and ISO 10993-5. The following tests were performed:

Test	Report number	Standard	Result	Conclusion
Cytotoxicity - Neutral Red Uptake	408/10 & Addendum May 3, 2010	ISO 10993-5 :2009	Test article treated extract cells were found to be 97% viable	Test sample extract is considered NON-CYTOTOXIC
Intracutaneous Reactivity	281/10	ISO 10993-10: 2009	Test article treated extract were found to have no erythema (Grade 0) or oedema (Grade 0) effects	Test sample extract is considered NON-IRRITANT
Sensitization test on guinea pig – Delayed contact hypersensitivity – Maximization method	1653 A-10 & Addendum September 30, 2010	ISO 10993-10: 2009	Test article treated extract were found to have no hypersensitivity effects (Grade 0 erythema)	Test sample extract is considered NON- SENSITIZING

From the tests' results, no adverse effects or sign of sensitization have been detected. The requirements of the test protocol were met.

From the results of the non clinical verification test and biocompatibility test, it has been concluded that BIONEN Needle Electrodes fulfill the products' specifications set for the design and are safe and effective needle electrodes comparable to the predicate devices.

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

Bionen SAS
c/o Ms. Allison Scott
Anson Group, LLC
11460 N. Meridian St., Ste 150
Carmel, IN 46032

OCT 7 2010

Re: K092973
Trade/Device Name: Disposable Concentric Needle Electrode
Disposable Monopolar/Subdermal Needle Electrode
Disposable Monopolar Needle Electrode
Regulation Number: 21 CFR 890.1385
Regulation Name: EMG Diagnostic Needle
Regulatory Class: Class II
Product Code: IKT, GXZ
Dated: September 22, 2010
Received: September 24, 2010

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 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,

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): K092973

Device Name: BIONEN Needle Electrodes

Indications for Use:

The BIONEN **Disposable Concentric Needle electrodes** are sterile electrodes indicated for recording muscle activity for Electro-myography (EMG) applications. The electrodes are for single patient use only.

The BIONEN **Disposable Monopolar/Subdermal Needle electrodes** are sterile electrodes indicated for recording muscle activity for Electro-myography (EMG) and/or Electroencephalography (EEG) applications. The electrodes are for single patient use only.

The BIONEN **Disposable Monopolar Needle electrodes** are sterile electrodes indicated for injection of Botulinum Toxin while recording muscle activity with Electro-myography (EMG) applications. The electrodes are for single patient use only.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K092973