K100382

SaluTunnel™ Nerve Protector

510(k) Summary

(as required by 21 CFR 807.92)

AUG - 5 2010

Submitter's Name and Address:

SaluMedica, LLC
931 E. Ponce de Leon Avenue, NE
Atlanta, GA 30306

Contact Person and Telephone Number:

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President
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Date Summary was Prepared:

August 2, 2010

Name of the Device:

Proprietary Name:	SaluTunnel™
Common Name:	Nerve Protector
Classification Name:	21 CFR 882.5275
Device Classification:	Class II, 84 Neurology
Product Code:	JXI

Substantial Equivalence:

SaluTunnel Nerve Protector is substantially equivalent in function and intended use to the following products which have been cleared to market under Premarket Notifications 510(k): SaluBridge Nerve Cuff (fka SaluMedica Nerve Cuff, K002098), Integra Lifesciences Corporation NeuroWrap™ Nerve Protector (K041620), and Collagen Matrix, Inc., NeuroMend™ Collagen Nerve Wrap (K060952). The basis for equivalence is demonstrated by the comparisons in the following table:

	SaluTunnel Nerve Protector (K100382)	SaluBridge Nerve Cuff (K002098)	NeuraWrap Nerve Protector (K041620)	NeuroMend Collagen Nerve Wrap (K060952)
Intended Use	Repair of peripheral nerve discontinuities in which there has been no substantial loss of nerve tissue	Repair of peripheral nerve discontinuities in which there has been no substantial loss of nerve tissue and where gap closure can be achieved by flexion of the extremity	Management of peripheral nerve injuries in which there has been no substantial loss of nerve tissue	Management of peripheral nerve injuries in which there has been no substantial loss of nerve tissue and where gap closure can be achieved by flexion of the extremity
Material	Salubria biomaterial	Salubria biomaterial	Collagen	Collagen
Design	Tube with longitudinal slit	Tube	Tube with longitudinal slit	Tube with longitudinal slit
Sizes	2-10mm ID 6.35cm length	2, 5, 10mm ID 6.35cm length	3, 5, 7 mm 2, 4 cm length	4, 6, 12mm ID 2.5, 5 cm length
Sterilization	Irradiation	Irradiation	Unknown	Unknown
Shelf Life	3 years	3 years	Unknown	Unknown
Packaging	Single device, hydrated, contained in preformed plastic tray with foil laminate lid in single unit carton	Single device, hydrated, contained in preformed plastic tray with foil laminate lid in single unit carton	Unknown	Unknown

Device Description:

The SaluTunnel Nerve Protector is a flexible tubular sheath developed to provide a protective environment for peripheral nerve repair after injury. The wall of the sheath has a longitudinal slit that allows SaluTunnel to be spread open for easy placement at the site of injury. The SaluTunnel Nerve Protector is designed to be interfaced between the nerve and its bed and, if necessary, to create a conduit for axonal growth across a nerve gap. SaluTunnel Nerve Protector is available in 2 through 10 mm inner diameter sizes. Each SaluTunnel device must be secured in place to prevent migration. Each SaluTunnel device should be chosen to be size appropriate.

The device is manufactured from Salubria biomaterial. Salubria is made from a polymer (polyvinyl alcohol) and saline. Each SaluTunnel is provided sterile, hydrated in saline for presentation onto the operative field, for single use only.

Intended Use:

SaluTunnel Nerve Protector is indicated for the management of peripheral nerve injuries in which there has been no substantial loss of nerve tissue.

Summary of Non-Clinical Data:

As required under Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, a summary of any information regarding safety and effectiveness of the device follows. Included in this section are descriptions of the testing, substantiating the safe and effective performance of the SaluTunnel Nerve Protector as well as its substantial equivalence to the predicate devices:

* Biocompatibility
* Design Verification (Bench-Top Testing)

The SaluTunnel Nerve Protector met all established requirements.

Biocompatibility:

Biocompatibility for SaluTunnel Nerve Protector is based on the biocompatibility of the SaluBridge Nerve Cuff. The two devices are manufactured from the exact material formulation using the exact manufacturing process. The devices differ only in the presence of a longitudinal slit in SaluTunnel Nerve Protector. The biocompatibility testing conducted for SaluBridge Nerve Cuff directly represents the biocompatibility of SaluTunnel Nerve Protector. Test results are summarized in the following table:

Test	Device	Method	Result
Cytotoxicity	SaluBridge	ISO MEM Elution	No evidence of cytotoxicity
Cytotoxicity	SaluTunnel - after 4 yrs RT aging	ISO MEM Elution	No evidence of cytotoxicity
Sensitization	SaluBridge	ISO Kligman Maximization	No evidence of sensitization
Intracutaneous Reactivity	SaluBridge	ISO Intracutaneous Injection	No evidence of irritation
Genotoxicity	SaluBridge	ISO Ames Mutagenicity	No evidence of mutagenicity
Genotoxicity	SaluBridge	ISO Chromosomal Aberration Assay	No evidence of clastogenicity
Implantation / Chronic Toxicity	SaluBridge	Rat Subcutaneous Implantation Study - 4 and 13 week	No evidence of local or systemic toxicity compared to silicone control implant

Design Verification (Bench-Top Testing):

Design Verification testing was conducted to evaluate the physical and mechanical properties of the SaluTunnel Nerve Protector. All testing was performed using units which were sterilized and met finished goods release requirements. Some testing, as noted below references testing conducted on the SaluBridge Nerve Cuff. The tests performed included:

* Dimensional / Visual Inspection (all sizes)
* Simulated Use
* Suture Retention Strength Test (SaluBridge)
* Sterilization Validation
* Packaging Verification: Ship Testing, Peel Strength, Vacuum Leak Analysis (SaluBridge)
* Shelf Life Determination: Accelerated and Real-Time Aging (SaluBridge)

The SaluTunnel Nerve Protector met all acceptance criteria for the tests conducted.

Conclusion:

SaluTunnel Nerve Protector is safe and effective under the proposed conditions of use and is substantially equivalent to its predicate devices. Safety and efficacy are supported through physician experience with the equivalent SaluBridge product, biocompatibility testing, and design verification testing.

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

SaluMedica, LLC
c/o Mr. Bob Braden
931 E Ponce De Leon Avenue
Atlanta, GA 30306

AUG - 5 2010

Re: K100382
Trade/Device Name: SaluTunnel™ Nerve Protector
Regulation Number: 21 CFR 882.5275
Regulation Name: Nerve cuff
Regulatory Class: Class II
Product Code: JXI
Dated: July 15, 2010
Received: July 19, 2010

Dear Mr. Braden:

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

K100382

Indications for Use

AUG - 5 2010

510(k) Number (if known): K100382

Device Name: SaluTunnel™ Nerve Protector

Indications For Use:

The SaluTunnel™ Nerve Protector is indicated for the management of peripheral nerve injuries in which there has been no substantial loss of nerve tissue.

Prescription Use ___X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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