INTEGRA
LIMIT UNCERTAINTY

K130557
APR 2 4 2014

510(K) SUMMARY

NeuraGen® 3D Nerve Guide Matrix

Submitter's name and address:

Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, NJ 08536 USA

Contact person and telephone number:

Stephen Beier
Senior Specialist, Regulatory Affairs
Telephone: 609.936.5436
Facsimile: 609.275.9445

Date Summary was prepared:

March 14, 2014

Name of the device:

Proprietary Name: NeuraGen® 3D
Common Name: Nerve guide matrix
Classification name: Nerve Cuff (21 CFR 882.5275)
Product Code: JXI

Substantial Equivalence:

NeuraGen® 3D is substantially equivalent in function and intended use to the predicate devices detailed in the following table.

510(k) Number	Product Code	Trade Name	Manufacturer
K011168	JXI	NeuraGen® Nerve Guide	Integra LifeSciences Corporation
K031069	JXI	Surgisis® Nerve Cuff	Cook Biotech Incorporated
K002098	JXI	SaluMedica™ Nerve Cuff	SaluMedica™ L.L.C.
K022127	KGN	Avagen Wound Dressing	Integra LifeSciences Corporation

Device Description:

NeuraGen® 3D Nerve Guide Matrix is a resorbable implant for the repair of peripheral nerve discontinuities. NeuraGen® 3D Nerve Guide Matrix provides a protective environment for peripheral nerve repair after injury, and is designed to isolate and protect the nerve and to create a conduit for axonal growth across a nerve gap. NeuraGen® 3D is composed of bovine Type I collagen conduit and a porous inner matrix comprised of collagen and glycosaminoglycan (chondroitin-6-sulfate). When hydrated, NeuraGen® 3D Nerve Guide Matrix is an easy to handle, soft, pliable, non-friable, collagen conduit containing a porous three-dimensional matrix. NeuraGen® 3D Nerve Guide Matrix is supplied sterile, non-pyrogenic, for single use in a variety of sizes.

Intended Use/Indications for Use:

The NeuraGen® 3D is indicated for repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity.

Substantial Equivalence Comparison:

The NeuraGen® 3D is similar in design and materials to the predicate devices: (K011168, K031069, K002098, and K022127). The following table details the substantial equivalence of NeuraGen® 3D to the identified predicate devices.

Product	Indications for Use	Physical Structure	Resorb-able	Range of Lengths	Range of Diameters	Material	Biocomp-atibility	Sterility
NeuraGen® 3D (proposed device)	NeuraGen® 3D is indicated for the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity.	Collagen conduit with a collagen-glycosaminoglycan inner matrix.	Yes.	Up to 6.35cm	1.5, 2, 3, 4, 5, 6, 7 mm inner tube diameters	Type I collagen and glycosaminoglycan (chondroitin-6-sulfate).	Yes.	Provided sterile.
NeuraGen® Nerve Guide	NeuraGen® Nerve Guide is indicated for the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity.	Collagen conduit.	Yes.	Up to 4cm	2, 3, 4, 5, 6, 7 mm inner tube diameters	Type I collagen.	Yes.	Provided sterile.
Avagen Wound Dressing	Avagen Wound Dressing is indicated for the management of wounds.	Collagen-glycosaminoglycan bilayer sheet.	Yes.	N/A; provided in sheet form.	N/A; provided in sheet form.	Type I collagen and glycosaminoglycan (chondroitin-6-sulfate).	Yes.	Provided sterile.
Surgisis® Nerve Cuff	The Surgisis® Nerve Cuff is indicated for the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity.	Porcine derived conduit (with or without slit)	Yes.	Up to 5cm	1.5, 2, 3, 4, 5, 6, and 7 mm inner tube diameters	Porcine small intestinal submucosa (SIS).	Yes.	Provided sterile.

Product	Indications for Use	Physical Structure	Resorb-able	Range of Lengths	Range of Diameters	Material	Biocomp-atibility	Sterility
SaluMedica™ Nerve Cuff	The SaluMedica™ Nerve Cuff with Saulbria™ Biomaterial is intended for use in repair of peripheral nerve discontinuities and where gap closure can be achieved by flexion of the extremity.	Polyvinyl Alcohol (PVA) Hydrogel conduit.	Yes.	6.35 cm	2, 5, and 10 mm inner tube diameters	Polyvinyl alcohol (PVA).	Yes.	Provided sterile.

Testing and Test Results:
The NeuraGen® 3D was determined to be substantially equivalent to the listed predicate devices after rigorous testing. Specifically, bench tests performed included confirmation of inner diameter, angle of occlusion, enzyme digestion, permeability, and chemical residual content. Furthermore, biocompatibility per ISO 10993 was performed to demonstrate that the device was both safe for implantation and to further establish equivalence among predicate devices. An animal study was conducted to study the efficacy of the product in a clinically relevant, critical sized nerve defect model in a rat.

Test	Results	Conclusions
Conduit Inner Diameter	Each tested conduit exhibited inner diameter within specified tolerance	Pass
Inner Matrix Pore Diameter	Average pore diameter of the inner matrix is within specified tolerance	Pass
Enzyme Digestion	Average enzyme digestion ≤99 AU/g	Pass
Residual Formaldehyde	Free formaldehyde residue ≤215 ug/device	Pass
Cytotoxicity – Agar Diffusion	No evidence of causing cell lysis or toxicity (Grade 0)	Non-cytotoxic
Sensitization Test	No evidence of causing delayed dermal contact sensitization	Non-sensitizer
Irritation Test	Test article mean score consistent with corresponding control mean score	Non-irritant
Acute Systemic Toxicity	No mortality and no evidence of systemic toxicity	Non-toxic
Sub-Acute Systemic Toxicity	No evidence of systemic toxicity and non-irritant	Non-toxic
Chronic Systemic Toxicity	No evidence of systemic toxicity and non-irritant	Non-toxic
Bacterial Reverse Mutation Test	Article extracts non-mutagenic to tested strains	Non-mutagenic
Chromosomal Aberration Assay	Extract equivocal	Equivocal results
Mouse Micronucleus Assay	Article in assay non-mutagenic	Non-mutagenic
Endotoxin-mediated pyrogenicity	Test article contained less than 0.06 EU/mL	Non-pyrogenic
Material-mediated pyrogenicity	Animal temperatures within USP limits	Non-pyrogenic
Ethylene Oxide Sterilization Residuals	Meets requirements of ISO 10993-7, passes each of four timepoints (24 hours, 30 days, total, daily intake)	Residual levels acceptable

Through the examination of the device performance properties and results of the testing and characterization activities, it was demonstrated that the proposed device was substantially equivalent to the predicate devices identified.

Conclusion:
The NeuraGen® 3D is substantially equivalent to the commercially marketed device, NeuraGen® Nerve Guide (K011168). Additional predicate devices to which this device demonstrates substantial equivalence include the Cook Biotech Surgisis® Nerve Cuff (K031069) the SaluMedica™ Nerve Cuff (K002098), and Avagen Wound Dressing (K022127).

The design expressed in this 510(k) Premarket Notification does not change the indications for use, intended use, or fundamental scientific technology of the predicate devices, nor does it raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 24, 2014

Integra LifeSciences Corporation
Mr. Stephen Beier
Senior Specialist, Regulatory Affairs
311 Enterprise Drive
Plainsboro, NJ 08536

Re: K130557
Trade/Device Name: NeuraGen 3D Nerve Guide Matrix
Regulation Number: 21 CFR 882.5275
Regulation Name: Nerve Cuff
Regulatory Class: Class II
Product Code: JXI
Dated: March 26, 2014
Received: March 27, 2014

Dear Mr. Beier:

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

Carlos L. Peña, PhD, MS
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 on last page.

510(k) Number *(if known)*
K130557

Device Name
NeuraGen 3D Nerve Guide Matrix

Indications for Use *(Describe)*
NeuraGen® 3D is indicated for the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Felipe Aguel -S Date: 2014.04.25 13:16:29 -04'00'

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