

U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (kml)

FOLDER: K032115 - 437 pages

COMPANY: POLYGANICS BV (POLYGANICS)

PRODUCT: CUFF, NERVE (JXI)

SUMMARY: Product: NEUROLAC NERVE GUIDE MODELS NG01-15/03, NG01-

020/03, NG01 025/03, NG01

DATE REQUESTED: Jun 7, 2016

DATE PRINTED: Jun 7, 2016

Note: Printed



Page 1 of 2

Neurolac® Nerve Guide Polyganics BV

Traditional 510(k) Premarket Notification



K032115

Summary of Safety and Effectiveness

Submitter:

Polyganics BV

L.J. Zielstraweg 1 9713 GX, Groningen The Netherlands www.polyganics.com

Jan Bart Hak, Ph.D.

Contact

Manager Clinical and Regulatory Affairs

Person:

: +31 50 588 6588

: +31 50 588 6599 Fax Mobile: +31 653 211 303 E-mail: hak@polyganics.com

Date Prepared: May 20, 2003

Tel

Provisions:

General

Trade Name: Neurolac® Nerve guide

Common Name: Nerve guide

Classification Name: Nerve Cuff, 21 CFR 882.5275

Device Classification: Class II

Predicate Devices:

Neurotube™

Neuroregen L.L.C.

K983007

NeuroGen™

Integra Life Sciences Corp. K011168

Performance **Standards**

For the Nerve Cuff performance, the FDA, under section 514 of the Food,

Drug and Cosmetic Act, has not established standards.

Indications for Use

The Neurolac® nerve guide is indicated for the reconstruction of a peripheral nerve discontinuity up to 20 mm in patients who have sustained a complete division of a nerve.

Neurolac® Nerve Guide Polyganics BV

Page 2 of 2



Device Description

Neurolac® is designed to be a flexible and transparent resorbable poly(DL-lactide-co-ε-caprolactone) tube to provide a protective environment for peripheral nerve regeneration after injury and to create a conduit to guide axonal growth across a nerve gap.

Neurolac® nerve guides are provided sterile in Tyvek pouch packages and retainer in a variety of sizes.

Performance Data:

The safety and effectiveness of the Neurolac nerve guides have been demonstrated via data collected from design verification tests and analyses. The design verification testing consisted of the following:

- In vitro suture retention testing
- In vitro degradation testing
- In vivo nerve function recovery

Summary of Substantial Equivalence

The design, fundamental technology and intended use (safety and efficacy) featured with the Neurolac® Nerve Guide are substantially equivalent to those featured with the competitor devices Neurotube™ (ref. 510(k) 983007; Neuroregen L.L.C.) and the NeuroGen™ Nerve Guide (ref. 510(k) 011168; Integra Life Sciences Corporation).

Biocompatibility, mechanical and physical property testing, in vitro degradation testing, and performance testing in an animal model provide reasonable scientific evidence that Neurolac® nerve guide is substantially equivalent to the predicate devices. Evaluation of the Polyganics Neurolac® Nerve guide based on biocompatibility testing, animal tests, results from literature and the comparison of the Neurolac® nerve guide with its predicate devices, shows that the Neurolac® nerve guide is safe for implantation.



OCT 1 0 2003

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Jan Bart Hak, Ph.D.

Manager, Clinical and Regulatory Affairs
Polyganics BV
L.J. Zielstraweg 1
9713 GX, Groningen
The Netherlands

Re: K032115

Trade/Device Name: Neurolac® Nerve Guide Regulation Number: 21 CFR 882.5275

Regulation Name: Nerve cuff

Regulatory Class: II Product Code: JXI Dated: July 3, 2003 Received: July 17, 2003

Dear Dr. Hak:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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 <u>Federal Register</u>.

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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and Neurological Devices Office of Device Evaluation Center for Devices and Radiological Health

Miriam C. Provost

Enclosure



Polyganics BV	POLYGANICS PROSPECTION OF THE PROPERTY OF THE
Indications for Use	Form
510(k) Number:	K032/15
Device Name:	Neurolac® Nerve Guide
Indications for Use:	
	leurolac nerve guide is indicated for the reconstruction of a peripheral nerventinuity up to 20 mm in patients who have sustained a complete division of a .
(PLEASE DO NOT NEEDED)	WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
Concurrence of CDF	RH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.10	OR Over-The-Counter Use
į. 3. 2. 31 IV 33 IV 10	(Optional Format 1-2-96)
	(Division Sign-Off)

Miriam C. Provost (Division Sign-Off)

510(k) Number _____

Division of General, Restorative and Neurological Devices

K032115 510(k) Number



LJ. Zielstraweg 1 97.3 GX Groningen The Netherlands

Telephone (31) 50 588 65 88 Telefax (+31) 50 588 65 99 E-mail mail@polyganics.com Internet www.polyganics.com

Mrs. M. Shulman Food and Drug Administration Center for Devices and Radiological Health Office of Device Evaluation Document Mail Center (HFZ-401) 9200 Corporate Blvd. Rockville, Maryland 20850 **USA**

Your ref.

: 510k# K032115

Our ref.

: Neurolac Nerve quide

Subject

: Correspondence address

Groningen, July 30, 2003

Dear Mrs. Shulman,

In relation to the premarket notification of our product Neurolac nerve guide with the 510(k) number K032115, we have noted that you use our US agent's address for correspondence.

I would greatly appreciate if it would be possible to send any future correspondence directly to me so that we can address any issue timely and efficiently. Our address is (as indicated on the submission cover sheet):

Polyganics BV L.J. Zielstraweg 1

Tel: +31 50 588 6588

9713 GX, Groningen

Fax: +31 50 588 6599

E-mail: hak@polyganics.com

The Netherlands

Sincerely yours,

Jan Bent Hak

Manager Clinical and Regulatory Affairs

Bank account

ABN AMRO Groningen 51.35.29.195 Commercial Reg. No. 02067151 VAT No. NL80.85.30,525.B01

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service Food and Drug Administration

,	Memorandum	_
Date:	10/22/03	
From:	DMC (HFZ-401)	
Subjec	Division Director: NE/DGRND	
Го:	Division Director: NE/DGRND	
	The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.	1
	Please review the attached document and return it to the DMC, with one of the statements check by ow.	ed
	Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.	•
	Additional information requires a new 510(k); however, the information submitted is incomplete; (Noitify company to submit a new 510(k); [Prepare the K30 Letter on the LAN]	
	No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, statement, change of address, phone number, or fax number).	
	CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440	
	Information requires a CLIA CATEGORIZATION; the complexity may remain the san as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)	ıe
	Additional information requires a CLIA CATEGORIZATION; however, the information submitted is incomplete; (call or fax firm)	ì
	No response necessary	
	This information should be returned to the DMC within 10 working days from the date of this memorandum.	
	Reviewed by: Daine B Barkous	
	Reviewed by: Dain B Balans Date: 10/28/03	

Draft #2 : 9/8/99 Draft #3: 1/3/00 Draft #4: 3/7/03

OCT 23

nmU



Polyganics BV L.J. Zielstraweg 1 9/13 GX Groningen The Nether ands

Telephone (31) 50 588 65 88 Telefax (+31) 50 588 65 99 E-mail mail@polyganics.com Internet www.polyganics.com

K032115/A2

David B. Berkowitz, Ph.D., V.M.D. Center for Devices and Radiological Health Food and Drug Administration 9200 Corporate Blvd. HFZ-410 Rockville, MD 20850 USA

Your ref.

: K032115

Our ref.

: 03-061

Subject

: Nerve Cuff, Neurolac

Groningen, Oct 8, 2003

Dear Mr. Berkowitz,

Please find enclosed the hardcopies of the files, which I've sent to you by electronic mail on Oct 8, 2003. This package includes the "510k file" and the instructions for use.

Of the 510k file, page 6, 8, 15, 17, 18 and 32 (this page is part of the 510k summary) are adjusted according to your recommendation.

Yours sincerely,

Jan Ban Hak, Ph.D.

Manager Clinical and Regulatory Affairs

5K¹³³

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FDA ADMINISTRATIVE FORMS

Premarket Submission Cover Sheet

Indications for Use Form



Submission Cover	Sheet					erika kalendari kalendari kalendari da
Date of Submission:	July 3, 2003	FI	DA Docume	nt Number:		
Section A		ype of Subn	nission			
PMA	PMA Supplement	Р	DP	510(k)		Meeting
o Original Submission o Modules Submission o Amendment o Report o Report Amendment	o Regular o Special o Panel Track o 30-day Supplement o 30-day Notice o 135-day Supplement o Real-time Review o Amendment to PMA Supplement	clinical tri o Intention to Notice of o Notice of O o Amendme o Report	DP Intent to start ials Insulation submit Insulation Interpolation Inter	v Original Submis v <u>Traditiona</u> o Special o Abbreviate o Additional Inforr o Traditiona o Special o Abbreviate	! ed mation I	o Pre-IDE meeting o Pre-PMA meeting o Pre-PDP meeting o 180-day meeting o Other (specify):
o Original Submission o Amendment o Supplement	ubmission o Original submission		Class II Exemption o Original submission o Additional information		tomatic nation sion nation	Other Submission Describe submission:
Section B		oplicant or S	ponsor			
Company / Institution Polyganics BV				nent registration		
Division name (if app	licable):		Phone number (include area code):			
Not Applicable			+31 50 58			
Street address:				er (include area	code):	
L.J. Zielstraweg 1			+31 50 58	8 6599		
City:	State/Province:		Country: Zip/Postal Cod			
Groningen	Groningen		The Neth	erlands	9713-	GX
Contact name:						
Jan-Bart Hak						·
Contact title:	d Danielston, Affains			mail address:		
	d Regulatory Affairs	residentia		/ganics.com	ornal retoric has all	estas i saucio Andelânes cottos y ve
	Submission Corre	spondent (i				
Company / Institution	name.		Establishment registration number: not applicable			
not applicable			Phone number (include area code):			
Division name (if applicable):						
not applicable Street address:			not applicable FAX number (include area code):			
not applicable		İ	not applica		coue).	
City:	State/Province:		Country:	אטוכ	Zin/Po	stal Code:
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not applicable						
Contact title:			Contact e-	mail address:		
not applicable			not applicable			
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Section D1 Reason	on for Submission – PMA, PDP, or l	A CONTRACTOR OF THE PROPERTY O
o New device	o Change in design, component, or specifica	o Location Change:
o Withdrawal	tions:	o Manufacturer
o Additional or expanded indications	o Software	o Sterilizer
o Licensing agreement	o Color Additive	o Packager
	o Material	o Distributor
	o Specifications	
	o Other (specify below):	
o Process Change:	o Labeling Change:	o Report submissions:
o Manufacturing	o Indications	o Annual or periodic
o Sterilization	o Instructions	o Post-approval study
o Packaging	 Performance characteristics 	o Adverse reaction
o Other (specify below):	o Shelf Life	o Device defect
``,	o Trade Name	o Amendment
	o Other (specify below):	
o Response to FDA correspondence:	o Change in ownersh	nip
o Request for applicant hold	o Change in correspond	·
o Request for removal of applicant l	• • • • • • • • • • • • • • • • • • • •	
o Request for extension		
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 Request to remove or add manufa 	acturing site	
o Request to remove or add manufa o Other reason (specify):	acturing site	
o Other reason (specify):		
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o Other reason (specify): Section D2		The state of the s
o Other reason (specify): Section D2 o New device	Reason for Submission – IDE	o Response to FDA letter concerning:
o Other reason (specify):	Reason for Submission - IDE	o Response to FDA letter concerning: o Conditional approval
o Other reason (specify): Section D2 o New device o Addition of institution o Expansion/extension of study	Reason for Submission — IDE o Change in: o Correspondent	o Response to FDA letter concerning: o Conditional approval o Deemed approved
o Other reason (specify): Section D2 o New device o Addition of institution o Expansion/extension of study o IRB certification	Reason for Submission — IDE o Change in: o Correspondent o Design	o Response to FDA letter concerning: o Conditional approval o Deemed approved o Deficient final report
o Other reason (specify): Section D2 o New device o Addition of institution o Expansion/extension of study o IRB certification o Request hearing	Reason for Submission — IDE o Change in: o Correspondent o Design o Informed Consent	o Response to FDA letter concerning: o Conditional approval o Deemed approved o Deficient final report o Deficient progress report
o Other reason (specify): Section D2 o New device o Addition of institution o Expansion/extension of study o IRB certification o Request hearing o Request waiver	o Change in: o Correspondent o Design o Informed Consent o Manufacturer	o Response to FDA letter concerning:
o Other reason (specify): Section D2 o New device o Addition of institution o Expansion/extension of study o IRB certification o Request hearing o Request waiver o Termination of Study	o Change in: o Correspondent o Design o Informed Consent o Manufacturer o Manufacturing process	o Response to FDA letter concerning:
o Other reason (specify): Section D2 o New device o Addition of institution o Expansion/extension of study o IRB certification o Request hearing o Request waiver o Termination of Study o Withdrawal of application	o Change in: o Correspondent o Design o Informed Consent o Manufacturer o Manufacturing process o Protocol – feasibility	o Response to FDA letter concerning:
o Other reason (specify): Section D2 o New device o Addition of institution o Expansion/extension of study o IRB certification o Request hearing o Request waiver o Termination of Study o Withdrawal of application o Unanticipated adverse effect	o Change in: o Correspondent o Design o Informed Consent o Manufacturer o Manufacturing process o Protocol – feasibility o Protocol – other	o Response to FDA letter concerning:
o Other reason (specify): Section D2 o New device o Addition of institution o Expansion/extension of study o IRB certification o Request hearing o Request waiver o Termination of Study o Withdrawal of application o Unanticipated adverse effect o Notification of emergency use	o Change in: o Correspondent o Design o Informed Consent o Manufacturer o Manufacturing process o Protocol – feasibility o Protocol – other	o Response to FDA letter concerning:
o Other reason (specify): Section D2 o New device o Addition of institution o Expansion/extension of study o IRB certification o Request hearing o Request waiver o Termination of Study o Withdrawal of application o Unanticipated adverse effect o Notification of emergency use o Compassionate use request	Reason for Submission – IDE o Change in:	o Response to FDA letter concerning:
o Other reason (specify): Section D2 o New device o Addition of institution o Expansion/extension of study o IRB certification o Request hearing o Request waiver o Termination of Study o Withdrawal of application o Unanticipated adverse effect o Notification of emergency use o Compassionate use request o Treatment IDE	Reason for Submission – IDE o Change in: o Correspondent o Design o Informed Consent o Manufacturer o Manufacturing process o Protocol – feasibility o Protocol – other o Sponsor o Report Submission:	o Response to FDA letter concerning:
o Other reason (specify): Section D2 o New device o Addition of institution o Expansion/extension of study o IRB certification o Request hearing o Request waiver o Termination of Study o Withdrawal of application o Unanticipated adverse effect o Notification of emergency use o Compassionate use request o Treatment IDE	Reason for Submission – IDE o Change in:	o Response to FDA letter concerning:
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o Other reason (specify): Section D2 o New device o Addition of institution o Expansion/extension of study o IRB certification o Request hearing o Request waiver o Termination of Study o Withdrawal of application o Unanticipated adverse effect o Notification of emergency use o Compassionate use request o Treatment IDE o Continuing availability request	o Change in:	o Response to FDA letter concerning:
Section D2 New device Addition of institution Expansion/extension of study IRB certification Request hearing Request waiver Termination of Study Unanticipated adverse effect Notification of emergency use Compassionate use request Treatment IDE Continuing availability request Other reason (specify):	o Change in:	o Response to FDA letter concerning:

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Section E		Additi	onal in	formation on	510(k) Submissio		4.4 等8.2 号录 性 等8.50	
Product codes of devices to which substantial equivalence is claimed: data:						, or statement concerning, safety and effectiveness		
1 JXI	2	3	•	4	v 510(k) summary attached o 510(k) statement			
Information on o	levices to which su	bstantial	equivaler	nce is claimed:				
510(k) Numb				or proprietary o	r model name	Manufacturer		
1. #K983007			Neurotube™			Neuroregen L.L.C.		
2. #K011168			Neuro(Gen™ Nerve G	uide	Integra Life Sci	ences Corp.	
					·-··	<u> </u>	· · · · · · · · · · · · · · · · · · ·	
	<u>.</u>	+						
Section F	Pr	oduct l	nforma	tion <u>—</u> Annlica	hle to All Applica	itions	ar over en balantele statistic	
Common or i	usual or classif	ication i	name. _I	Jerve Cuff	pie to Yu Whbiios	ILIONS SECTIONS	(1) 自由 (1) (1) (1) (1) (1) (1) (1) (1) (1) (1)	
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Trade or prop	orietary or mod	el name	9			Model number		
Neurolac® N	lerve Guide					NG01-015/03		
Neurolac® N	lerve Guide	·				NG01-020/03		
Neurolac® N	lerve Guide					NG01-025/03		
Neurolac® N	lerve Guide					NG01-030/03		
·								
FDA document r	umbers of all prior	r related s	submissio 3	ns (regardless of c	outcome):	5	16	
Data included in				<u>_</u>	<u> </u>	1		
	· · · · · · · · · · · · · · · · · · ·		atory test		 Animal trials Application 	o Humar	and the state of the control of the state of	
Product code:		uuci:Oi		R. section:	anie io vii vhhiic	Device class:		
JXI				CFR 882.5275		o Class I	v Class II	
UXI			- ' `	JI IN 002.021 5		o Class III	o Unclassified	
			_			Device class:		
						o Class I	o Class II	
			İ			o Class III	o Unclassified	
	•					Device class:		
						o Class !	o Class II	
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				Therapeutic I				
						reconstruction of pe	eripheral nerve	
discontinuity t	up to 20 mm in	patient	s who h	nave sustained	a complete divisio	n of a nerve.		

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			FDA Document Number:	
Section H	/lanufact	uring / Packaging	/ Sterilization Sites	
ν Original	•	v Manufacturer	o Contrac	t sterilizer
o Add o Delete		o Contract manufacture	er o Repack	ager / relabeler
Company/institution name:			Establishment registration numb	er:
Polyganics BV			Not registered	·
Division name (if applicable):		:	Phone number (include area cod	te):
(,			+31 50 588 6588	,
Street address:			Favoriant and the clouds are a delay	
L.J. Zielstraweg 1			Fax number (include area code) +31 50 588 6599	
City:	State/Pro		Country:	Zip/Postal Code:
Groningen Contact Name:	Gronin	gen	The Netherlands	9713-GX
(see Section B)				
Contact Title:			Contact e-mail address:	
(see Section B)		14	(see Section B)	
v Original o Add o Delete		o Manufacturer o Contract manufacturer		et sterilizer (EtO) ager / relabeler
b) (4)			·	agor i ioraboro.
Company/institution name:			Establishment registration number	er:
Division name (if applicable):		İ	Phone number (include area code	e):
			()	
Street address:			Fav number (include area code):	
On our addition.			Fax number (include area code): ()	
City	Photo /D		0	
City:	State/Provi	ince:	Country:	Zip/Postal Code:
Contact Name:				
Contact Title:			Contact e-mail address:	

08-Oct-03



	POLYGANICS Polymetri Indovations in tissue recovery
Indications for Use	Form
510(k) Number:	
Device Name:	Neurolac® Nerve Guide
Indications for Use:	
	eurolac nerve guide is indicated for the reconstruction of a peripheral nerve tinuity up to 20 mm in patients who have sustained a complete division of a
(PLEASE DO NOT NEEDED)	WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
Concurrence of CDR	ન, Office of Device Evaluation (ODE)
Prescription Use_ (Per 21 CFR 801.109	OR Over-The-Counter Use
	(Optional Format 1-2-96)
	(Division Sign-Off)
	510(k) Number



APPLICANT STATEMENTS

Truth and Accuracy Certification

Substantial Equivalence Terminology Statement



PREMARKET NOTIFICATION

Truthful And Accurate Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as a Regulatory Affairs representative of Polyganics BV, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

J.B. Hak, Ph.D.
Manager Clinical and Regulatory Affairs
Polyganics BV
L.J. Zielstraweg 1
9713-GX Groningen
The Netherlands

Date

Premarket Notification [510(k)] Number



Substantial Equivalence Terminology Statement

USE OF THE TERM "SUBSTANTIALLY EQUIVALENT

The use of the term "substantially equivalent" as used herein is intended to be a determination of substantial equivalence under the Federal Food, Drug, and Cosmetic Act, as Amended, and relates to the fact that the product can be marketed without premarket approval or reclassification. Such a determination is not intended to have any bearing whatsoever on the resolution of patent infringement suits or other patent matters.



Section 1: GENERAL INFORMATION

Applicant

Polyganics BV L.J. Zielstraweg 1 9713-GX Groningen The Netherlands

FDA Establishment Registration Number: Not Registered yet

Contact Person

Jan Bart Hak, Ph.D.

Manager Clinical and Regulatory Affairs

Polyganics BV L.J. Zielstraweg 1 9713-GX Groningen The Netherlands

+31 50 588 6588 Tel: Fax: +31 50 588 6599 E-mail: hak@polyganics.com

Device Name

Trade Name	Common Name	Classification Name
Neurolac Nerve Guide	Nerve Guide	Nerve Cuff
		21 CFR 882.5275

Device Classification

Classification Name:

Classification name is Class II "Nerve Cuff" (Ref. Codes of

882.5275)

Class:

Federal regulations, title 21 Description: (a) Identification. A nerve cuff is - Food and Drugs, Part 882 a tubular silicone rubber sheath used to en-Neurological devices, case a nerve for aid in repairing the nerve subpart F - Neurological (e.g., to prevent ingrowth of scar tissue) and Therapeutic devices, Sec for capping the end of the nerve to prevent the formation of neuroma (tumors).

Manufacturing **Facility**

Polyganics BV L.J. Zielstraweg 1 9713-GX Groningen The Netherlands

FDA Establishment Registration Number: not registered



Sterilization Facility (EtO)



Performance Standards / Special Controls No performance standards are indicated for this product.

Purpose of Premarket Notification The reason for this premarket notification is to inform the Food and Drug Administration (FDA) of our intent to market the Polyganics Neurolac Nerve Guide.

Predicate Devices The following table provides information on the predicate devices.

Trade Name	Manufacturer	510k#	Concurrence Date	Substantial Equivalence
Neurotube™	Neuroregen L.L.C.	K983007 Traditional APPENDIX D	03/22/1999	The tube provides an optimal environment for longitudinal nerve axon growth of the peripheral nerve. For single use only in patients with a peripheral nerve injury where the nerve gap is more than or equal to 8 mm, but less than or equal to 3 cm.
NeuroGen™ Nerve Guide	Integra Life Sciences Corp.	K011168 Traditional APPENDIX E	06/22/2001	NeuroGen™ Nerve guide is indicated for repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity.

Software Validation and Certification

This section is not applicable, since the Neurolac Nerve Guide does not utilize software in the performance of its intended use.

Kit Certifica-

This section is not applicable.



Class III Certi- fication	This section is not applicable. The Neurolac Nerve Guide is a Class II device
510(k) Sum- mary	A summary of safety and effectiveness for the Neurolac Nerve Guide is provided in APPENDIX A.



Section 2: DEVICE DESCRIPTION

Drawings

Please refer to APPENDIX B of this 510(k) premarket notification for an engineering drawing of the subject device.

Intended Use

The Neurolac nerve guide is indicated for the reconstruction of a peripheral nerve discontinuity up to 20 mm in patients who have sustained a complete division of a nerve.

There are no known contraindications.

For FDA administrative purposes, the intended use of the Polyganics Neurolac Nerve Guide is also documented in a separate form that can be found at the beginning of the 510(k) notification in the section entitled "FDA Administrative Forms"

Device Description

The Neurolac nerve guide is composed of the bioresorbable copolyester poly(DL-lactide-ε-caprolactone). The Neurolac nerve guide provides guidance and protection to regenerating axons.

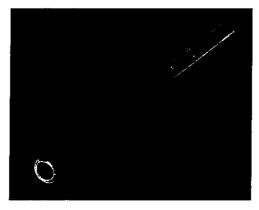


Figure 1. Example of the Neurolac nerve guide

The Neurolac nerve guide elicits a minimal acute inflammatory reaction of the surrounding tissue, which is followed by gradual encapsulation of the tube by fibrous tissue. Degradation of the Neurolac nerve guide occurs through hydrolysis leading to gradual reduction of molecular weight. The Neurolac nerve guide retains its initial mechanical properties up to 8 weeks, whereafter rapid loss of mechanical strength and gradual mass loss occur. The final degradation products, lactic acid and ω -hydroxy hexanoic acid, are resorbed, metabolized and excreted by the body. Animal studies demonstrated that a Neurolac nerve guide is resorbed within 16 months.

The Neurolac nerve guide inner diameter is indicated on the label, and is packed in a tray placed in a Tyvek pouch. The Neurolac nerve guide is indicated for single-use.

The Polyganics Nerve Guide further consists of:

08-Oct-03



- Packaging Labeling
- IFU



Section 3: PROPOSED LABELING

Subject Device Labeling

The following proposed labeling for the subject device Neurolac Nerve Guide is provided in APPENDIX C:

- Outer label (Carton)
- Inner label (Pouch)
- Pre-printed carton text and graphics
- Instructions for Use

Intended Use of the Subject Device

The Neurolac nerve guide is indicated for the reconstruction of a peripheral nerve discontinuity up to 20 mm in patients who have sustained a complete division of a nerve.

Promotional Materials

At present, no promotional materials are available for the subject device.



Section 4: COMPARATIVE INFORMATION

Background

The Polyganics Neurolac nerve guide is a biodegradable tube for the repair of transected peripheral nerves.

Intended Use

The Indications for Use for the subject and predicate devices are described in the table below.

Subject Device	Indication for Use		
Neurolac	The Neurolac nerve guide is indicated for the reconstruction of a peripheral nerve discontinuity up to 20 mm in patients who have sustained a complete division of a nerve.		

Predicate De- vice	Indication for Use
Neurotube™ APPENDIX D	The Neurotube is intended for single use in patients with an injury to a peripheral nerve, in which the nerve gap is more than or equal to 8 mm but less than or equal to 3 cm. The nerve gap may be created primarily at the time of injury or created secondarily at the time of exploration of failed primary repair
NeuroGen™ APPENDIX E	NeuroGen Nerve Guide is indicated for repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity.

teristics

Device Charac- The technological characteristics (i.e., design, dimensions material etc.) of the subject Neurolac Nerve Guide and the predicate devices are presented in the table below. The table provides a comparison, demonstrating that the Neurolac is substantially equivalent to the currently marketed predicate device.



Device Characteristics of the Subject and Predicate devices

Characteristics General	Subject Device	Predicate Devices		
· .	Neurolac®	Neurotube™	NeuroGen ™	
510(k) Reference	This 510(k)	K983007	K011168	
Sterile	Sterile device	Sterile device	Sterile device	
Single Use	Single-use	Single-use	Single-use	
Contents packaging	Nerve guide and instruc- tions for use		Nerve guide and instruc- tions for use	
Length Inner Diameter (In.) Material	b)(4) Priduct specs			
Biodegradable	Yes	Yes	Yes	
Animal derived	No	Yes	No	
	Peripheral Nerve disconti- nuity	Peripheral Nerve disconti- nuity	Peripheral Nerve disconti- nuity	
Transparent	Yes	No	No	

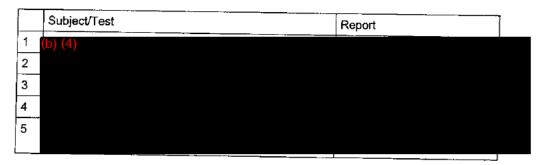
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Section 5: PERFORMANCE VERIFICATION

Performance Verification

The performance testing on the Neurolac Nerve Guide was conducted to verify that the meets performance characteristics. The following performance tests were conducted:



Testing was performed on finished sterile products. The test results were all favorable for the Neurolac Nerve guide. The complete performance test reports have been attached as APPENDIX F.



(b)(4) Testing	



(b)(4) Testing	



(b)(4) Testing	-		



(b)(4) Testing		

08-Oct-03



(b)(4) Testing	

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(b)(4) Testing		



(b)(4) Testing	

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Section 6: BIOCOMPATIBILITY

	(b)(4) Testing		
Background			
Testing			

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Section 7: STERILIZATION AND PYROGENICITY INFORMATION



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Section 8: PACKAGING AND SHELF-LIFE INFORMATION

Introduction

The Neurolac nerve guides are packaged in a tray (mechanical protection) and subsequently sealed in a Tyvek/PET-PE pouch. The packaging does comply with standards ISO11607.

Packaging Description

The Neurolac nerve guides are packaged in a tray serving as a mechanical protection.

The tray together with a Neurolac nerve guide are packaged in a Tyvek/PET-PE pouch. The pouch carriers a pouch label on the PET-PE layer of the pouch.

The pouch with product in the tray is packaged together with the instructions for use in a carton box. The carton box carries the carton box label.

Product Shelf – Life

The Neurolac nerve guide has a shelf-life (Use By date) of 12 months.



APPENDIX A: 510(K) SUMMARY OF SAFETY AND EFFECTIVINESS



510(k) Summary of Safety and Effectiveness

Submitter:

Polyganics BV L.J. Zielstraweg 1

9713 GX, Groningen The Netherlands www.polyganics.com

Jan Bart Hak, Ph.D.

Contact Person:

Manager Clinical and Regulatory Affairs

Tel : +31 50 588 6588 : +31 50 588 6599 Fax

Mobile: +31 653 211 303 E-mail: hak@polyganics.com

Date Prepared:

May 20, 2003

General Provisions:

Trade Name: Neurolac® Nerve guide

Common Name: Nerve guide

Classification Name: Nerve Cuff, 21 CFR 882.5275

Device Classification: Class II

Predicate Devices:

Neurotube™

Neuroregen L.L.C.

K983007

NeuroGen™

Integra Life Sciences Corp. K011168

Performance Standards

For the Nerve Cuff performance, the FDA, under section 514 of the Food,

Drug and Cosmetic Act, has not established standards.

Indications for Use

The Neurolac® nerve guide is indicated for the reconstruction of a peripheral nerve discontinuity up to 20 mm in patients who have sustained a complete

division of a nerve.



Device Description

Neurolac® is designed to be a flexible and transparent resorbable poly(DL-lactide-co-ε-caprolactone) tube to provide a protective environment for peripheral nerve regeneration after injury and to create a conduit to guide axonal growth across a nerve gap.

Neurolac® nerve guides are provided sterile in Tyvek pouch packages and retainer in a variety of sizes.

Performance Data:

The safety and effectiveness of the Neurolac nerve guides have been demonstrated via data collected from design verification tests and analyses. The design verification testing consisted of the following:

- In vitro suture retention testing
- In vitro degradation testing
- In vivo nerve function recovery

Summary of Substantial Equivalence

The design, fundamental technology and intended use (safety and efficacy) featured with the Neurolac® Nerve Guide are substantially equivalent to those featured with the competitor devices Neurotube™ (ref. 510(k) 983007; Neuroregen L.L.C.) and the NeuroGen™ Nerve Guide (ref. 510(k) 011168; Integra Life Sciences Corporation).

Biocompatibility, mechanical and physical property testing, in vitro degradation testing, and performance testing in an animal model provide reasonable scientific evidence that Neurolac® nerve guide is substantially equivalent to the predicate devices. Evaluation of the Polyganics Neurolac® Nerve guide based on biocompatibility testing, animal tests, results from literature and the comparison of the Neurolac® nerve guide with its predicate devices, shows that the Neurolac® nerve guide is safe for implantation.



APPENDIX B: DEVICE DRAWING



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APPENDIX C: DEVICE LABELING

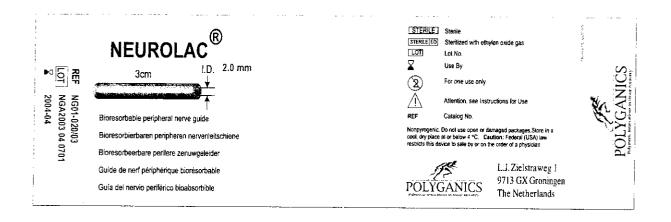
Subject device: Neurolac Nerve Guide

DRAFT



DEVICE LABELING

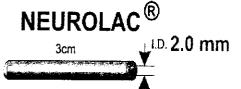
Carton, DRAFT





DEVICE LABELING

Inner label pouch, DRAFT



Bioresorbable peripheral nerve guide
Bioresorbierbaren peripheren nervenleitschiene
Bioresorbeerbare perifere zenuwgeleider
Guide de nerf périphérique biorésorbable
Guía del nervio periférico bioabsorbible







REF

NG01-020/03

LOT

NGA2003 04 2501



2004-04

Nonpyrogenic. Do not use open or damaged packages. Store in a cool, dry place at or below 4 °C. Caution: Federal (USA) law restricts this device to sale by or on the order of a physician



L.J. Zielstraweg 1 9713 GX Groningen The Netherlands



DEVICE LABELING

Instructions for Use, DRAFT

PG002a 2003-01-09 MM024 IFU EN version 19



APPENDIX D: PREDICATE DEVICE NEUROTUBE™

Neuroregen L.L.C.

510(k): K983007



APPENDIX E: PREDICATE DEVICE NEUROGEN™

Integra Life Sciences Corporation

510(k): K011168



APPENDIX F: PERFORMANCE TEST REPORTS

Suture retention testing
In vitro degradation testing
Nerve function recovery: sciatic nerve model
Neurolac nerve guide versus autologous nerve graft
Functional nerve recovery after bridging a 15 mm nerve gap with a Neurolac nerve guide



Suture retention testing



In vitro degradation testing



Nerve function recovery: sciatic nerve model



Neurolac nerve guide versus autologous nerve graft



Functional nerve recovery after bridging a 15 mm nerve gap with a Neurolac nerve guide



APPENDIX G: BIOCOMPATIBILITY DATA

Cytotoxicity
Irritation
Sensitization
Hemocompatibility
Acute systemic toxicity
Pyrogenicity
Mutagenicity /genotoxicity
Sub chronic toxicity
Carcinogenicity
Chronic toxicity
Reproductive toxicity
Implantation



Cytotoxicity



Irritation



Sensitization



Hemocompatibility



Acute systemic toxicity



Pyrogenicity



Mutagenicity /genotoxicity



Sub chronic toxicity



Carcinogenicity

Chronic toxicity

Reproductive toxicity



Implantation

Polyganics' Neurolac® bioresorbable nerve guide



CAUTION: Federal (USA) law restricts this device to sale by STERILE, Sterilized with ethylene oxide gas. For single use or on the order of a physician. only. Do not autoclave.

Neurolac® peripheral nerve guide

Description

The Neurolac nerve guide is composed of the bioresorbable copolyester poly(DL) actide-c-canciactore). The Neurolac nerve guide provides guidence and protection to regenerating axons. The Neurolac nerve guide elicits a minimal acute inflammatory reaction of the surrounding tissue, which is followed by gradual errospetulation of the tube by Birosus issue. Degradation of the Neurolac nerve guide occurs through hydrolysis leading to gradual reduction of molecular weight. The Neurolac nerve guide rapid loss of mechanical strength and gradual mass loss occur. The final degradation products, lactic acid and e-hydroxy hexanolic acid, are resorbed, metabolized and excreted by the body. Animal studies demonstrated that a Neurolac nerve guide is retains its initial mechanical properties up to 8 weeks, whereafter resorbed within 16 months. on the ch. The The Neurolac nerve guide inner diameter is indicated on label, and is packed in a tray placed in a Tyvek pouch. Neurolac nerve guide is indicated for single-use.

The Neurolac nerve guide is indicated for the reconstruction of a peripheral nerve discontinuity up to 20 mm in patients who have sustained a complete division of a nerve.

Contraindications

There are no known contraindications

- ics BV will not be responsible for any direct or consequential damages or expenses resulting from re-use of (or any part of) the Neurolac nerve guide:

 Off the Neurolac nerve guides bas been opened or damaged. Discard open unused nerve guides.

 The Neurolac nerve guide should only be used by physical or the Neurolac nerve guide should only be used by physical parts. The Neurolac nerve guide is for single use only. Do not restellize or re-use. Structural integrity andfor function may be impaired trucyth cleaning, restellization, or re-use and may cause adverse patient reactions. Accordingly, Polygan-
- cians who are trained in nerve defect repair techniques. Accordingly, Polyganics BV will not be responsible for any direct or consequential damages or expenses resulting from use by untrained personnel. The physician should consult recent literature on current medical practice on peripheral nerve repair;
- Nerve regeneration may be suboptimal in elderly, malnour-ished or debilated patients or in patients suffering from can-cer, anaemia, obesity, diabetes, infection or other conditions which may delay wound healing, infected wounds, or mod-erate tissue inflammatory response characteristic of foreign body response.

- Use prior to "Use by date";
- Store in dark, dry place at or below 4°C (39°F);
 Do not expose the nerve guide to organic solvents (e.g. chloroform, acetone);
 Do not use absorbable sutures for fixation of the nerve
- stumps into the nerve guide;

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Version 21 US, 08-Oct-2003





Prevent compression and/or kinking of the Neurolac after the procedure. The use of a protective splint is recom

Adverse effects

Adverse events associated with the use of a Neurolac nerve guide may include but are not limited to:

- Failure to provide adequate nerve regeneration at sites where too much tension or compression occurs;
 - Failure to provide adequate/complete nerve regeneration; Transitory local irritation

 - Infection;
- Delayed wound healing. Allergy;

The pouch is opened in such a way that the tray remains sterile Opening of the package

The tray can be opened by sliding the lid. By clasping the nerve guide at one of its ends between a pair of tweezers, it can be taken from the tray. The lid contains a ruler that may be used as a reference to estimate the gap length or nerve stump diameter.

Surgical Procedure

- Surgically expose the injured nerve.
 Resect the injured segment distally and proximally until a nerve stump is identified with no residual intrafascicular
- Measure the length of the defect with all joints in an ex-NOTE: Do not crush the nerve stumps as this can cause extrusion of intra-fascicular components. က်
 - If the gap length is between 0 and 20 mm, the injured nerve can be reconstructed with a Neurolac nerve guide. tended position.
- Select the Neurolac nerve guide with the proper Internal dameter ဖြင့်
 - NOTE: It is essential that the internal nerve guide diameter is slightly larger than the diameter of the transected nerve to guarantee optimal nerve regeneration.

Descriptions or specifications in Polyganics BV printed matter, including this publication, are meant solely to generally describe the product at the time of manufacture and do not constitute any express warrantles.

Polyganics BV will not be responsible for any direct, inciden-tal, or consequential damages resulting from reuse of the

consequential damages resulting from

tal, or co product.

Polyganics BV be liable for any direct, incidental, or consequential damages other than as expressly provided by specific law. No person has the authority to bind Polyganics to any representation or warranty except as specifically set forth herein.

DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY There is no express or implied warranty, including without limitation any implied warranty of merchantability or fitness for a particular purpose. On the Defendant for a particular purpose, on the Polyganics product(s) described in this publication. Under no circumstances shall

Telephone Fax

Polyganics BV L.J. Zielstraweg 1 9713 GX Groningen

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Sterilized by ethylene oxide

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STERILE | EO

Sterile product

STERILE

Lot number

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Cut the selected nerve guide with a pair of scissors or a knife so that the nerve guide is 1 cm longer than the nerve gap.

Under some circumstances immobilization of the nerve ends, as to avoid tension on the nerve ends, may be employed at the discretion of the surgeon. To secure adequate fixation of the nerve ends in the nerve guide, the accepted surgical technique of flat, square ties with additional throws as warranted by surgical circumstance and the experience of the surgeon, is required.

Suturing Technique

- approximately 1 minute before implantation. This will make Place the Neurolac nerve guide in warm saline (37°C) for the tube more flexible and ease needle passage during su-
- suture) first through the tube from the outside to the inside and then transversally and superficially through the epineurium and back through the tube from the inside to the Suture the Neurolac nerve guide by passing the suture (8-0 ۸i
- outside, after which a tle is made (Fig. 1.1-1.3). When positioning optimization of the nerve ends in the nerve guide is required, it is recommended to place a second suure in the same nerve end (Fig. 1.4). Pull the proximal nerve stump into the nerve guide. еŝ
 - 4

Polyganics' Neurolac® bioresorbable nerve guide



Refer to accompanying instruc-

tions for use.

Use by

NOTE: it is recommended that the nerve ends are pulled into the tube for at least 3 mm for optimal nerve regenera-

using a solution containing 1000 units of heparin per 100 ml of normal saline Fill the tube with heparinized saline,

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- Subsequently, use the same procedure, to pull the distal A minimum space of 5 mm should be left between the nerve nerve stump into the nerve guide
- Fill any remaining space with heparinized saline (Fig 1.6) by injecting along the nerve into the lumen of the tube or by penetrating the tube (not the nerve). ends in the nerve guide. ω.

For single use only

 (\bowtie)

Catalog number

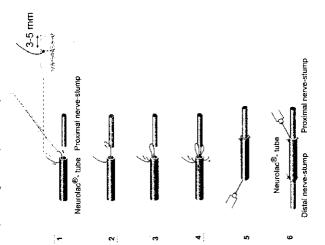


Figure 1. Schematic representation of suture technique suturing the nerve ends into the nerve guide.

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lumen since this may hinder nerve recovery.

CAUTON: The areve guide should be implanted and sutured with all joints in an extended position as to assure that no tension occurs on the proximal or distal nerve end CAUTION: Ensure that no blood enters the nerve guide when joints are being mobilized. Close the wound and splint to prevent kinking for the first three postoperative weeks. Long-term compression of the nerve guide should be avoided. Patients may be administered oral antibiotics for the first post-operative week. oi

Dispose contaminated implantation and packaging materials utilizing standard hospital procedures and universal precautions for bio-hazardous waste.

Neurolac® is a registered trademark of Potyganics

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Polyganics BV, 2003



OCT 1 0 2003

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Jan Bart Hak, Ph.D.
Manager, Clinical and Regulatory Affairs
Polyganics BV
L.J. Zielstraweg 1
9713 GX, Groningen
The Netherlands

Re: K032115

Trade/Device Name: Neurolac® Nerve Guide

Regulation Number: 21 CFR 882.5275

Regulation Name: Nerve cuff

Regulatory Class: II Product Code: JXI Dated: July 3, 2003 Received: July 17, 2003

Dear Dr. Hak:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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 <u>Federal Register</u>.

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); 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.

Page 2 - Jan Bart Hak, Ph.D.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Miriam C. Provost

Enclosure



Polyganics BV			POLYGANICS Projection of the distribution of t
Indications for Us	se Form		
510(k) Number:	K032/19	5	
Device Name:	Neurolac® Nerve Gui	<u>de</u>	
Indications for Use	: :		
The disc ner	continuity up to 20 mm in p	ndicated for the reconstructi atients who have sustained	on of a peripheral nerve a complete division of a
(PLEASE DO N	OT WRITE BELOW THIS	S LINE - CONTINUE ON	N ANOTHER PAGE IF
Concurrence of C	DRH, Office of Device Eva	luation (ODE)	
Prescription Use_ (Per 21 CFR 801.	· · · · · · · · · · · · · · · · · · ·	Over-The-Counter Use (Optional Fo	
	(Division Sign-	Off)	

(Division Sign-Off)

Division of General, Restorative and Neurological Devices

510(k) Number <u>K032/15</u>

510(k) Number _____

Food and Drug Administration Center for Devices and Radiological Health Office of Device Evaluation Document Mail Center (HFZ-401) 9200 Corporate Blvd. Rockville, Maryland 20850

July 21, 2003

POLYGANICS BV C/O VIKTOR J. NICKOLSON 33 RIVER ST. UNIT 813 HOBOKEN. NJ 07030

ATTN: VIKTOR J. NICKOLSON

510(k) Number: K032115 Received: 17-JUL-2003

Product: NEUROLAC NERVE GUIDE

MODELS NG01-15/03, NG01-020/03, NG01 025/03, NG01-030/03

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA)(Public Law 107-250), authorizes FDA to collect user fees for premarket notification submissions. (For more information on MDUFMA, you may refer to our website at http://www.fda.gov/oc/mdufma).

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMICA. If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301)594-1190.

Sincerely yours,

Marjorie Shulman Supervisory Consumer Safety Officer Office of Device Evaluation Center for Devices and Radiological Health

Food and Drug Administration Center for Devices and Radiological Health Office of Device Evaluation Document Mail Center (HFZ-401) 9200 Corporate Blvd. Rockville, Maryland 20850

July 09, 2003

POLYGANICS BV C/O VIKTOR J. NICKOLSON 33 RIVER ST. UNIT 813 HOBOKEN, NJ 07030

ATTN: VIKTOR J. NICKOLSON

510(k) Number: K032115 Received: 09-JUL-2003

Product: NEUROLAC NERVE GUIDE User Fee ID Number: 83121-15/03,

NG01-020/03, NG01-025/03,

The Food and Drug Administration (FDA) Center for Devices and Radiological Heath (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250), specifies that a submission shall be considered incomplete and shall not be accepted for filing until fees have been paid (Section 738(f)). Our records indicate that you have not submitted the user fee payment information and therefore your 510(k) cannot be filed and has been placed on hold. The payment information we need in order to begin the review of your 510(k) includes, the user fees cover sheet with the payment ID faxed to the Office of Financial Management at (301) 827-9213 and a check mailed to:

By Regular Mail
Food and Drug Administration

P.O. Box 956733 St. Louis, MO 63195-6733. By Private Courier (e.g., Fed Ex, UPS, etc.)

U.S. Bank 956733 1005 Convention Plaza St. Louis, MO 63101 (314) 418-4983

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should also be faxed to CDRH at (301) 594-2977 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at http://www.fda.gov/oc/mdufma.

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file an application with FDA or what type of application to file, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (301)443-6597 or its toll-fee number (800)638-2041, or contact them at their Internet address http://www.fda.gov/cdrh/dsmamain.html, or you may submit a 513(g) request to the Document Mail Center at the address above. If you have any questions concerning the contents of this letter, you may contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman Consumer Safety Officer Office of Device Evaluation Center for Devices and Radiological Health



Polyganics BV L.J. Zielstraweg 1 9713 GX Groningen The Netherlands

Telephone (31) 50 588 65 88 Telefax (-31) 50 588 65 99 E-mail mail@polyganics.com Internet www.polyganics.com

United States Agent Notification Information processing and Office Automation Branch Office of Compliance Center for Devices and Radiological Health 9200 Corporate Blvd, HFZ-308 Rockville, MD 20850-4015 USA

Our ref. : 03-029/PG002a Neurolac Subject : U.S. Agent Notification

Groningen, July 3, 2003

Dear Sir, Madam,

I am providing the following information to comply with the U.S. agent requirement for foreign establishments.

Establishment information

Name: Polyganics BV.

Registration #: Not yet registered, 510k process ongoing.

Street address: L.J. Zielstraweg 1 City: Groningen Zip code: 9713 GX

Country: The Netherlands Official Correspondent: Jan Bart Hak, Ph.D. Phone +31 50 588 6588 Fax +31 50 588 6599 E-mail hak@polyganics.com Web: www.polyganics.com

All our orders and deliveries are subject to our General Terms and Conditions, registered at the Chamber of Commerce in Groningen under number 02067151. On request a copy will be sent free of charge.

39 SIX IV NG JJJ Groningen 51.35 ? reg. No. 022 85.22 Bank account ABN AMRO Groningen 51.35.29.195 Commercial Reg. No. 02067151 VAT No. NL80.85.30.525.801

United States Agent Information

Name: Viktor J. Nickolson Street address: 33 River St. Unit 813

City: Hoboken State: NJ Zip code: 07030

Country: United States of America

Phone +1 201 656 4123

E-mail victorj.nickolson@mac.com

Yours sincerely,

Jan Bart Hak, Ph.D. Manager Clinical and Regulatory affairs



510(k) PREMARKET NOTIFICATION TABLE OF CONTENTS

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DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION

PAYMENT IDENTIFICATION NUMBER:



MEDICAL DEVICE USER FEE COVER SHEET

Write the Payment Identification Number on your check

See Instructions Before Completing This Cover Sheet

can be found at the following website: http://www.fda.gov/oc/mdufma. The following three actions must be taken to properly submit your premarket application and fee payment:

A completed cover sheet must accompany each original premarket application or supplement listed in Box 3 of this cover sheet. Other premarket application types do not require the use of this cover sheet; see list in the instructions. Payment instructions and fee rates FAX a copy of this completed cover sheet to the Food and Drug Administration at (301) 827-9213 before payment is sent. Include a copy of this completed cover sheet with the check made payable to the Food and Drug Administration and mail them to the Food and Drug Administration, P.O. Box 956733, St. Louis, MO 63195-6733. (Note: In no case should payment be submitted with the premarket application.) Also remember that the Payment Identification Number must be written on the check. If you prefer to send a check by a courier, the courier may deliver the check and cover sheet to: US Bank, 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.) Include a copy of this completed cover sheet in volume one of the premarket application when submitting to the Food and Drug Administration at either the CBER or CDRH Document Mail Center. COMPANY NAME AND ADDRESS (Include name, street 2. CONTACT NAME JAN-BART HAK address, city, state, country, and post office code) 2.1 E-MAIL ADDRESS POLYGANICS BV hak@polyganics.com L.J. ZIELSTRAWEG 1 GRONINGEN, 9713 GX 2.2 TELEPHONE NUMBER (Include area code) +31 50 588 6588 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) 2,3 FACSIMILE (FAX) NUMBER (Include area code) +31 50 588 6599 3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma) 3.1 Select one of the types below: Select an application type: Original Application Premarket notification (510(k)); except for third party reviews ☐ Biologic License Application (BLA) Supplement Types: Efficacy (BLA) Premarket Approval Application (PMA) Modular PMA Panel Track (PMA, PMR, PDP) Real-Time (PMA, PMR, PDP) Product Development Protocol (PDP) L 180-day (PMA, PMR, PDP) ☐ Premarket Report (PMR) 4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status.) YES, I meet the small business criteria and have submitted the Mo, I am not a small business required qualifying documents to FDA 4.1 If Yes, please enter your Small Business Decision Number: 5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. The sole purpose of the application is to support This application is the first PMA submitted by a qualified small conditions of use for a pediatric population business, including any affiliates, parents, and partner firms The application is submitted by a state or federal This biologic application is submitted under section 351 of the government entity for a device that is not to be Public Health Service Act for a product licensed for further distributed commercially manufacturing use only 6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

36

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

M NO

☐ YES



Submission Cover S							
Date of Submission:	July 3				nt Number:		
Section A			pe of Subm		1		
PMA	PMA	Supplement	PC	OP .	510(k)		Meeting
o Original Submission o Modules Submission o Amendment o Report o Report Amendment	o 30- o 30- o 135 o Rea o Am		o Notice of C o Amendmer o Report	ope stent to start als submit Completion completion at to PDP	v Original Submis: v <u>Traditional</u> o Special o Abbreviate o Additional Inforn o Traditional o Special o Abbreviate	od nation ed	o Pre-IDE meeting o Pre-PMA meeting o Pre-PDP meeting o 180-day meeting o Other (specify):
o Original Submission o Amendment o Supplement	o Ori		o Original su o Additional i	bmission nformation	evaluation of Au Class III Design o Original submiss o Additional inforn	nation sion	Other Submission Describe submission:
Section B		Ap	plicant or S			-	
Company / Institution	name	:		Establishment registration number:			
Polyganics BV				Not regis			
Division name (if applicable):				Phone number (include area code):			
Not Applicable				+31 50 58			·
Street address:					ber (include area	a code):	
L.J. Zielstraweg 1				+31 50 58	38 6599		
City:		State/Province:		Country:		Zip/Po	ostal Code:
Groningen		Groningen		The Neth	erlands	9713-	GX
Contact name:							
Jan-Bart Hak							
Contact title:		<u> </u>		Contact e	-mail address:		
Manager Clinical an	d Reg	ulatory Affairs		hak@pol	yganics.com		
Section C		ıbmission Corre	spondent (i				
Company / Institution			•		ment registration	numbe	er:
not applicable				not applic	_		
Division name (if app	licable):			mber (include ar	ea code	e):
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Street address:			FAX number (include area code):				
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Section D1 Reaso	n for Submission - PMA, PDP, or	
New device	o Change in design, component, or specifi	
o Withdrawal	tions:	o Manufacturer
Additional or expanded indications	o Software	o Sterilizer
Licensing agreement	o Color Additive	o Packager
•	o Material	o Distributor
	 Specifications 	
	o Other (specify below):	
o Process Change:	o Labeling Change:	o Report submissions:
o Manufacturing	o Indications	o Annual or periodic
o Sterilization	o Instructions	o Post-approval study
o Packaging	o Performance characteristics	o Adverse reaction
O Other (specify below):	o Shelf Life	o Device defect
o Guior (apoonly below).	o Trade Name	o Amendment
	o Other (specify below):	÷ · · · · · · · · · · · · · · · · · · ·
Response to FDA correspondence:	o Change in owne	ershin
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o Request for extension		
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Section D2 New device Addition of institution Expansion/extension of study IRB certification Request hearing	Reason for Submission – IDE o Change in: o Correspondent o Design o Informed Consent o Manufacturer	o Conditional approval o Deemed approved o Deficient final report o Deficient progress report o Deficient investigator report
Section D2 New device Addition of institution Expansion/extension of study IRB certification Request hearing Request waiver	Reason for Submission – IDE o Change in: o Correspondent o Design o Informed Consent o Manufacturer o Manufacturing process	o Conditional approval o Deemed approved o Deficient final report o Deficient progress report o Deficient investigator report o Disapproval
Section D2 New device Addition of institution Expansion/extension of study IRB certification Request hearing Request waiver Termination of Study	o Change in:	o Conditional approval o Deemed approved o Deficient final report o Deficient progress report o Deficient investigator report o Disapproval o Request extension of time to re-
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Section D2 New device Addition of institution Expansion/extension of study IRB certification Request hearing Request waiver Termination of Study Withdrawal of application Unanticipated adverse effect Notification of emergency use	Reason for Submission – IDE o Change in:	o Conditional approval o Deemed approved o Deficient final report o Deficient progress report o Deficient investigator report o Disapproval o Request extension of time to respond to FDA
Other reason (specify): Section D2 New device Addition of institution Expansion/extension of study IRB certification Request hearing Request waiver Termination of Study Withdrawal of application Unanticipated adverse effect	Reason for Submission – IDE o Change in: o Correspondent o Design o Informed Consent o Manufacturer o Manufacturing process o Protocol – feasibility o Protocol – other o Sponsor o Report Submission:	o Conditional approval o Deemed approved o Deficient final report o Deficient progress report o Deficient investigator report o Disapproval o Request extension of time to respond to FDA
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Section E		Addit	ional In	formation on !	510(k) Submissio	ons	
	of devices to which				Summary of, or state data:	ement concerning, safe	ty and effectiveness
1 JXI	2	3	odalyc	4	v 510(k) summary a o 510(k) statement	ttached	
Information on o	levices to which su	bstantia	l equivale	nce is claimed:			
510(k) Numb				or proprietary o	r model name	Manufacturer	
1. #K983007			Neurot			Neuroregen L	
2. #K011168	 }		Neuro	Gen™ Nerve G	Suide	Integra Life So	ciences Corp.
					<u>-</u>		
					· · · · · · · · · · · · · · · · · · ·		
Section F	Dr	oduct	Informs	tion - Applica	able to All Applic	ations	
Section F	usual or classif	Jostier	nomo:	Nonio Cuff	ible to All Applio	ations	
Common or	usual or classii	icatior	name.	Nerve Cuii			
Trade or pro	prietary or mod	lel nan	ne		***************************************	Model number	
	Nerve Guide					NG01-015/03	
	Nerve Guide					NG01-020/03	
	Nerve Guide					NG01-025/03	
	Nerve Guide					NG01-030/03	
Trou. Grades .							
FDA document	numbers of all pric	r related	Lsubmissi	ons (regardless of	outcome):		
1 N.A.	2	rolatot	3	one (regulations of	4	5	6
Data included in	n submission:	v Lab	oratory tes	tina	v Animal trials	o Hum	an trials
Section G	Pro				able to All Appli	cations	
Product code:				.R. section:		Device class:	
JXI			21	CFR 882.5275		o Class I	ν Class II
			-			o Class III	 Unclassified
			<u> </u>			Device class:	
[o Class I	o Class II
						o Class III	o Unclassified
		·				Device class:	
						o Class I	o Class II
						o Class III	o Unclassified
Classification pa	anel: Neurology	/ (Neu	rologica	ıl Therapeutic	Devices)		
						e reconstruction of	peripheral nerve
					d a complete divis		
The use of a	Neurolac nerv	e guid	e is cont	raindicated in p	patients with know	n hypersensitivity	or allergies to its
components				•		·	-



FDA ADMINISTRATIVE FORMS

Premarket Submission Cover Sheet

Indications for Use Form



			FDA Document Number	er:	
Section H	Manufacti	uring / Packaging	/ Sterilization Si	ites	-
v Original o Add o Delete		v Manufacturer o Contract manufacture	•	o Contract st	erilizer er / relabeler
Company/institution name: Polyganics BV		o comment mental actions	Establishment registral Not registered		
Division name (if applicable):			Phone number (include +31 50 588 6588	e area code)	
Street address: L.J. Zielstraweg 1			Fax number (include at +31 50 588 6599	rea code):	
City: Groningen	State/Pro-		Country: The Netherlands		Zip/Postal Code: 9713-GX
Contact Name: (see Section B)					
Contact Title: (see Section B)			Contact e-mail address (see Section B)	3:	
v Original o Add o Delete		o Manufacturer o Contract manufacture			terilizer (EtO) er / relabeler
(4)					
o Original		o Manufacturer		o Contract s	erilizer
o Add o Delete		o Contract manufacture		o Repackage	
Company/institution name:			Establishment registrat	tion number:	
Division name (if applicable):			Phone number (include area code):		
Street address:		Fax number (include area code):		·	
City:	State/Prov				
	State/Fig	vince:	Country:		Zip/Postal Code:
Contact Name:	State/F100	/ince:	Country:		Zip/Postal Code:



	Dalvineta in rozation of tissie retwery
Indications for Us	e Form
510(k) Number:	
Device Name:	Neurolac® Nerve Guide
Indications for Use	:
disc nerv The	Neurolac nerve guide is indicated for the reconstruction of a peripheral nerve ontinuity up to 20 mm in patients who have sustained a complete division of a re. use of a Neurolac nerve guide is contraindicated in patients with known hysensitivity or allergies to its components.
(PLEASE DO NO NEEDED)	OT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
Concurrence of CE	DRH, Office of Device Evaluation (ODE)
Prescription Use_ (Per 21 CFR 801.1	OR Over-The-Counter Use
	(Division Sign-Off)
	510(k) Number



APPLICANT STATEMENTS

Truth and Accuracy Certification

Substantial Equivalence Terminology Statement



PREMARKET NOTIFICATION

Truthful And Accurate Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as a Regulatory Affairs representative of Polyganics BV, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

J.B. Hak, Ph

Manager Ofinical and Regulatory Affairs

Polyganics BV

L.J. Zielstraweg 1 9713-GX Groningen

The Netherlands

Premarket Notification [510(k)] Number



Substantial Equivalence Terminology Statement

USE OF THE TERM "SUBSTANTIALLY EQUIVALENT

The use of the term "substantially equivalent" as used herein is intended to be a determination of substantial equivalence under the Federal Food, Drug, and Cosmetic Act, as Amended, and relates to the fact that the product can be marketed without premarket approval or reclassification. Such a determination is not intended to have any bearing whatsoever on the resolution of patent infringement suits or other patent matters.



Section 1: GENERAL INFORMATION

Applicant

Polyganics BV L.J. Zielstraweg 1 9713-GX Groningen The Netherlands

FDA Establishment Registration Number: Not Registered yet

Contact Person

Jan Bart Hak, Ph.D.

Manager Clinical and Regulatory Affairs

Polyganics BV L.J. Zielstraweg 1 9713-GX Groningen The Netherlands

Tel: +31 50 588 6588 Fax: +31 50 588 6599 E-mail: hak@polyganics.com

Device Name

Trade Name	Common Name	Classification Name
Neurolac Nerve Guide	Nerve Guide	Nerve Cuff
		21 CFR 882.5275

Device Classification

Classification Name:

Classification name "Nerve Cuff" (Ref. Codes of

Food and Drugs, Part 882 Neurological devices, subpart F - Neurological Therapeutic devices, Sec

Federal regulations, title 21

882.5275)

Class:

is Class II

Description: (a) Identification. A nerve cuff is a tubular silicone rubber sheath used to encase a nerve for aid in repairing the nerve (e.g., to prevent ingrowth of scar tissue) and for capping the end of the nerve to prevent the formation of neuroma (tumors).

Manufacturing **Facility**

Polyganics BV L.J. Zielstraweg 1 9713-GX Groningen The Netherlands

FDA Establishment Registration Number: not registered



Sterilization Facility (EtO)



Performance Standards / Special Controls No performance standards are indicated for this product.

Purpose of Premarket Notification The reason for this premarket notification is to inform the Food and Drug Administration (FDA) of our intent to market the Polyganics Neurolac Nerve Guide.

Predicate Devices The following table provides information on the predicate devices.

Trade Name	Manufacturer	510k #	Concurrence Date	Substantial Equivalence
Neurotube™	Neuroregen L.L.C.	K983007 Traditional APPENDIX D	03/22/1999	The tube provides an optimal envi- ronment for longitudinal nerve axon growth of the peripheral nerve. For single use only in patients with a peripheral nerve injury where the nerve gap is more than or equal to 8 mm, but less than or equal to 3 cm.
NeuroGen™ Nerve Guide	Integra Life Sciences Corp.	K011168 Traditional APPENDIX E	06/22/2001	NeuroGen™ Nerve guide is indicated for repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity.

Software Validation and Certification

This section is not applicable, since the Neurolac Nerve Guide does not utilize software in the performance of its intended use.

Kit Certification This section is not applicable.



Class III Certification

This section is not applicable. The Neurolac Nerve Guide is a Class II device fication

A summary of safety and effectiveness for the Neurolac Nerve Guide is provided in APPENDIX A.



Section 2: DEVICE DESCRIPTION

Drawings

Please refer to APPENDIX B of this 510(k) premarket notification for an engineering drawing of the subject device.

Intended Use

The Neurolac nerve guide is indicated for the reconstruction of a peripheral nerve discontinuity up to 20 mm in patients who have sustained a complete division of a nerve.

The use of a Neurolac nerve guide is contraindicated in patients with known hypersensitivity or allergies to its components.

For FDA administrative purposes, the intended use of the Polyganics Neurolac Nerve Guide is also documented in a separate form that can be found at the beginning of the 510(k) notification in the section entitled "FDA Administrative Forms"

Device Description

The Neurolac nerve guide is composed of the bioresorbable copolyester poly(DL-lactide- ϵ -caprolactone). The Neurolac nerve guide provides guidance and protection to regenerating axons, and prevent ingrowth of fibrous tissue into the nerve gap during nerve regeneration from the proximal to the distal nerve stump of the transected nerve.

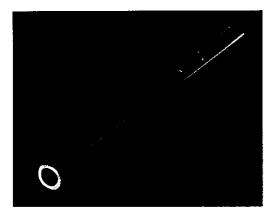


Figure 1. Example of the Neurolac nerve guide

The Neurolac nerve guide elicits a minimal acute inflammatory reaction of the surrounding tissue, which is followed by gradual encapsulation of the tube by fibrous tissue. Degradation of the Neurolac nerve guide occurs through hydrolysis leading to gradual reduction of molecular weight. The Neurolac nerve guide retains its initial mechanical properties up to 8 weeks, whereafter rapid loss of mechanical strength and gradual mass loss occur. The final degradation products, lactic acid and ω -hydroxy hexanoic acid, are resorbed, metabolized and excreted by the body. Animal studies demonstrated that a Neurolac nerve guide is resorbed within 16 months.

The Neurolac nerve guide inner diameter is indicated on the label, and is packed in a tray placed in a Tyvek pouch. The Neurolac nerve guide is indi-



cated for single-use.

The Polyganics Nerve Guide further consists of:

- Packaging
- Labeling
- IFU



Section 3: PROPOSED LABELING

Subject Device Labeling

The following proposed labeling for the subject device Neurolac Nerve Guide is provided in APPENDIX C:

- Outer label (Carton)
- Inner label (Pouch)
- Pre-printed carton text and graphics
- Instructions for Use

Intended Use of the Subject Device

The Neurolac nerve guide is indicated for the reconstruction of a peripheral nerve discontinuity up to 20 mm in patients who have sustained a complete division of a nerve.

The use of a Neurolac nerve guide is contraindicated in patients with known hypersensitivity or allergies to its components.

Promotional Materials

At present, no promotional materials are available for the subject device.



Section 4: COMPARATIVE INFORMATION

Background

The Polyganics Neurolac nerve guide is a biodegradable tube for the repair of transected peripheral nerves.

Intended Use

The Indications for Use for the subject and predicate devices are described in the table below.

Subject Device	Indication for Use		
Neurolac	The Neurolac nerve guide is indicated for the reconstruction of a peripheral nerve discontinuity up to 20 mm in patients who have sustained a complete division of a nerve. The use of a Neurolac nerve guide is contraindicated in patients with known hypersensitivity or allergies to its components.		

Predicate De- vice	Indication for Use		
Neurotube™ APPENDIX D	The Neurotube is intended for single use in patients with an injury to a peripheral nerve, in which the nerve gap is more than or equal to 8 mm but less than or equal to 3 cm. The nerve gap may be created primarily at the time of injury or created secondarily at the time of exploration of failed primary repair		
NeuroGen™ APPENDIX E	NeuroGen Nerve Guide is indicated for repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity.		

Device Characteristics

The technological characteristics (i.e., design, dimensions material etc.) of the subject Neurolac Nerve Guide and the predicate devices are presented in the table below. The table provides a comparison, demonstrating that the Neurolac is substantially equivalent to the currently marketed predicate device.



Device Characteristics of the Subject and Predicate devices

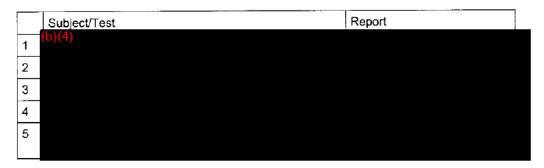
Characteristics General	Subject Device	Predicate Devices		
	Neurolac®	Neurotube™	NeuroGen ™	
510(k) Reference	This 510(k)	K983007	K011168	
Sterile	Sterile device	Sterile device	Sterile device	
Single Use	Single-use	Single-use	Single-use	
Contents packaging		Nerve guide and instruc- tions for use	Nerve guide and instruc- tions for use	
Length Inner Diameter (In.) Material	(b)(4)			
Biodegradable	Yes	Yes	Yes	
Animal derived	No	Yes	No	
Indication	Peripheral Nerve discontinuity	Peripheral Nerve disconti- nuity	Peripheral Nerve disconti- nuity	
Transparent	Yes	No	No	



Section 5: PERFORMANCE VERIFICATION

Performance Verification

The performance testing on the Neurolac Nerve Guide was conducted to verify that the meets performance characteristics. The following performance tests were conducted:



Testing was performed on finished sterile products. The test results were all favorable for the Neurolac Nerve guide. The complete performance test reports have been attached as APPENDIX F.



(b)(4)Testing	

Neurolac® Nerve	Guide
Polyganics BV	

Traditional 510(k) Premarket Notification



b)(4)Testing	



(b)(4)Testing	



(b)(4)Testing	 	
(b)(4) (esting		

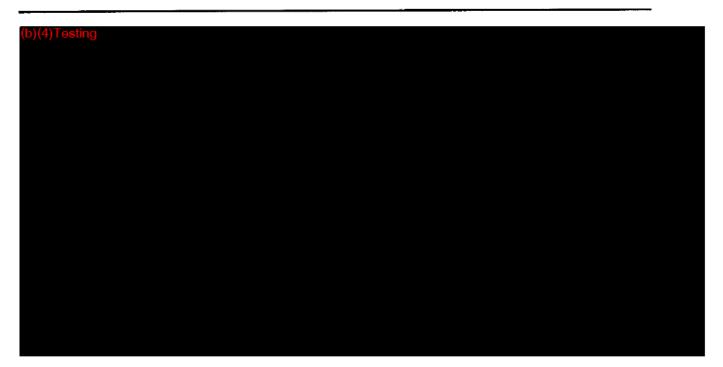


(b)(4)Testing	



(b)(4)Testing	







Section 6: BIOCOMPATIBILITY





Section 7: STERILIZATION AND PYROGENICITY INFORMATION





Section 8: PACKAGING AND SHELF-LIFE INFORMATION

Introduction

The Neurolac nerve guides are packaged in a tray (mechanical protection) and subsequently sealed in a Tyvek/PET-PE pouch. The packaging does comply with standards ISO11607.

Packaging Description

The Neurolac nerve guides are packaged in a tray serving as a mechanical protection.

The tray together with a Neurolac nerve guide are packaged in a Tyvek/PET-PE pouch. The pouch carriers a pouch label on the PET-PE layer of the pouch.

The pouch with product in the tray is packaged together with the instructions for use in a carton box. The carton box carries the carton box label.

Product Shelf – Life

The Neurolac nerve guide has a shelf-life (Use By date) of 12 months.



APPENDIX A: 510(K) SUMMARY OF SAFETY AND EFFECTIVINESS



510(k) Summary of Safety and Effectiveness

Submitter:

Polyganics BV L.J. Zielstraweg 1 9713 GX, Groningen The Netherlands www.polyganics.com

Jan Bart Hak, Ph.D.

Contact Per-

Manager Clinical and Regulatory Affairs

son:

Tel : +31 50 588 6588 Fax : +31 50 588 6599 Mobile: +31 653 211 303 E-mail: hak@polyganics.com

Date Prepared:

May 20, 2003

General Pro-

visions:

Trade Name: Neurolac® Nerve guide

Common Name: Nerve guide

Classification Name: Nerve Cuff, 21 CFR 882,5275

Device Classification: Class II

Predicate Devices:

Neurotube™

Neuroregen L.L.C.

K983007

NeuroGen™

Integra Life Sciences Corp. K011168

Performance **Standards**

For the Nerve Cuff performance, the FDA, under section 514 of the Food. Drug and Cosmetic Act, has not established standards.

Indications for Use

The Neurolac® nerve guide is indicated for the reconstruction of a peripheral nerve discontinuity up to 20 mm in patients who have sustained a complete division of a nerve.

The use of a Neurolac nerve guide is contraindicated in patients with known hypersensitivity or allergies to its components.



Device Description

Neurolac® is designed to be a flexible and transparent resorbable poly(DL-lactide-co-ε-caprolactone) tube to provide a protective environment for peripheral nerve regeneration after injury and to create a conduit to guide axonal growth across a nerve gap.

Neurolac® nerve guides are provided sterile in Tyvek pouch packages and retainer in a variety of sizes.

Performance Data:

The safety and effectiveness of the Neurolac nerve guides have been demonstrated via data collected from design verification tests and analyses. The design verification testing consisted of the following:

- In vitro suture retention testing
- In vitro degradation testing
- In vivo nerve function recovery

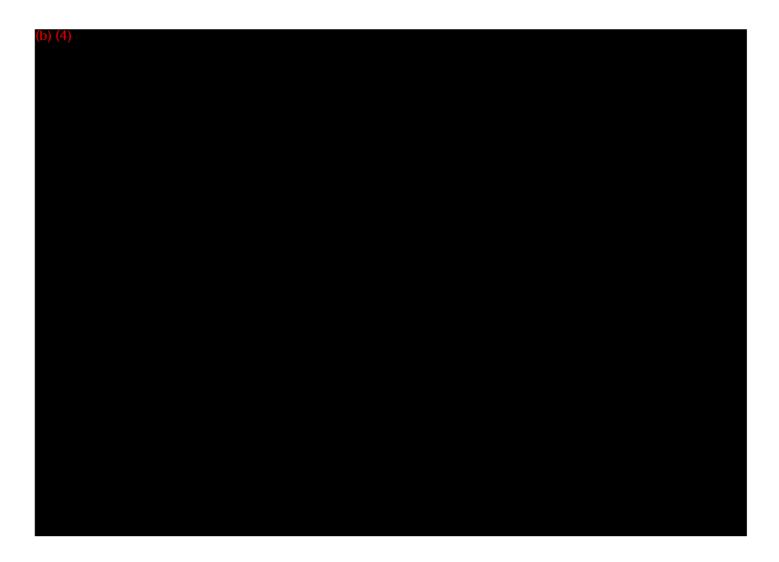
Summary of Substantial Equivalence

The design, fundamental technology and intended use (safety and efficacy) featured with the Neurolac® Nerve Guide are substantially equivalent to those featured with the competitor devices Neurotube™ (ref. 510(k) 983007; Neuroregen L.L.C.) and the NeuroGen™ Nerve Guide (ref. 510(k) 011168; Integra Life Sciences Corporation).

Biocompatibility, mechanical and physical property testing, in vitro degradation testing, and performance testing in an animal model provide reasonable scientific evidence that Neurolac® nerve guide is substantially equivalent to the predicate devices. Evaluation of the Polyganics Neurolac® Nerve guide based on biocompatibility testing, animal tests, results from literature and the comparison of the Neurolac® nerve guide with its predicate devices, shows that the Neurolac® nerve guide is safe for implantation.



APPENDIX B: DEVICE DRAWING





APPENDIX C: DEVICE LABELING

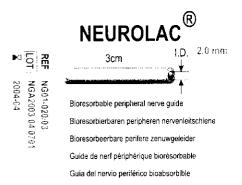
Subject device: Neurolac Nerve Guide

DRAFT



DEVICE LABELING

Carton, DRAFT





L.J.Zielstraweg 1

The Netherlands

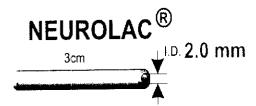
9713 GX Groningen





DEVICE LABELING

Inner label pouch, DRAFT



Bioresorbable peripheral nerve guide
Bioresorbierbaren peripheren nervenleitschiene
Bioresorbeerbare perifere zenuwgeleider
Guide de nerf périphérique biorésorbable
Guia del nervio periférico bioabsorbible







REF

NG01-020/03

LOT

NGA2003 04 2501



2004-04

Nonpyrogenic Do not use open or damaged backages Store in a cool, dry place at or below 4 °C. **Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician



L.J. Zielstraweg 1 9713 GX Groningen The Netherlands



DEVICE LABELING

Instructions for Use, DRAFT

PG002a 2003-01-09 MM024 IFU EN version 19



TERILE. Sterilized with ethylene oxide gas. For single use

AUTION: Federal (USA) law restricts this device to sale by r on the order of a physician.

leurolac® peripheral nerve guide

uide provides guidance and protection to regenerating axons, no prevents ingrowth of fibrous tissue into the nerve gap during erve regeneration from the proximal to the distal nerve sturnp of he Neurolac® nerve guide is composed of the biorescrbable opolyester poly(DL-lactide-ε-caprolactone). The Neurolac nerve ne transected nerve.

saction of the surrounding tissue, which is followed by gradual neapsulation of the tube by fibrous tissue. Degradation of the leurolac nerve guide occurs through hydrolysis leading to radual reduction of molecular weight. The Neurolac nerve guide he final degradation products, lactic acid and w-hydroxy hexa-oic acid, are resorbed, metabolized and excreted by the body, unimal studies demonstrated that a Neurolac nerve guide is he Neurolac nerve guide elicits a minimal acute inflammatory stains its initial mechanical properties up to 8 weeks, whereafter apid loss of mechanical strength and gradual mass loss occur.

he Neurolac nerve guide inner diameter is indicated on the stel, and is packed in a tray placed in a Tyvek pouch. The feurolac nerve guide is indicated for single-use.

esorbed within 16 months.

he Neurolac nerve guide is indicated for the reconstruction of a eripheral nerve discontinuity up to 20 mm in patients who have ustained a complete division of a nerve.

ontraindications

he use of a Neurolac nerve guide is contraindicated in patients ith known hypersensitivity or allergies to its components.

The Neurolac nerve guide is for single use only. Do not resterlize or re-use, Structural integrity and/or function may be impaired through cleaning, resterlization, or re-use and may cause adverse patient reactions. Accordingly, Polyganiss S Will into be responsible for any direct or consequential damages or expenses resulting from re-use of (or any part of) the Neurolac nerve guide. Varnings

Sterile unless package has been opened or damaged. Discard open unused nerve guides.

clans who are trained in nerve defect repair techniques. Accordingly, Polyganics BV will not be responsible for any direct or consequential damages or expenses resulting from use by untrained personnel. The physician should consult recent itlerature on current medical practice on peripheral The Neurolac nerve guide should only be used by physinerve repair.

Persons with altergic reactions to the biodegradable material or breakdown products may suffer an attergic response to this implant.

which may delay wound healing, infected wounds, or moderate tissue inflammatory response characteristic of foreign Nerve regeneration may be suboptimal in etderly, matnourished or debilated patients or in patients suffering from cancer, anaemia, obesity, diabetes, infection or other conditions

Precautions

POLYGANICS

- Use prior to "Use by date"; ٠

- Store in dark, dry place at or below 4°C (39°F);
 Store in dark, dry place at or below 4°C (39°F);
 Do not expose the nerve guide to organic solvents (e.g. chloroform; acetons).
 Do not use absorbable sutures for fixation of the nerve stumps into the nerve guide;
 - Avoid crushing, chmping, kinking or other damage due to application of surgical instruments such as forceps, needleholders and scissors or during handling of the device; Avoid tension on the nerve ends;
- Prevent compression and/or kinking of the Neurolac after the procedure. The use of a protective splint is recommended.

Adverse effects

Adverse events associated with the use of a Neurolac® nerve guide may include but are not limited to:

- Failure to provide adequate nerve regeneration at sites where too much tension or compression occurs;
 - Failure to provide adequate/complete nerve regeneration

 - Transitory local imitation
- Infection
- Delayed wound healing

Opening of the package

The pouch is opened in such a way that the tray remains sterile. The tray can be opened by siding the lid. By classing the nerve guide at one of its ends between a pair of tweezers, it can be taken from the tray. The lid contains a ruler that may be used as a

reference to estimate the gap length or nerve stump diameter

N

Surgical Procedure

Resect the injured segment distally and proximally until a nerve stump is identified with no residual intrafascicular Surgically expose the injured nerve.

NOTE: Do not crush the nerve stumps as this can cause extrusion of intra-fascicular components.

- Measure the length of the defect with all joints in an ex-က
- If the gap length is between 0 and 20 mm, the injured nerve

4.

- Select the Neurolac nerve guide with the proper internal can be reconstructed with a Neurolac nerve guide ιci
 - NOTE: it is essential that the internal nerve guide diameter is slightly larger than the diameter of the transected nerve diameter.

to guarantee optimal nerve regeneration.

Cut the selected nerve guide with a pair of scissors or a knife so that the nerve guide is 1 cm longer than the nerve ø

Under some circumstances immobilization of the nerve ends, as to avoid tension on the nerve ends, may be employed at the nerve ends in the nerve guide, the accepted surgical technique of flat, square ties with additional throws as warranted by surgical discretion of the surgeon. To secure adequate fixation of the circumstance and the experience of the surgeon, is required.

Suturing Technique

Place the Neurolac nerve guide in warm saline (37°C) for approximately 1 minute before implantation. This will make the tube more flexible and ease needle passage during sutring. Souture the Neurolac nerve guide by passing the suture (8-0 suture) first through the tube from the outside to the inside and then transversally and superficially through the epi-

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Page

Polyganics BV, 2003

Version 19, 23-Jun-2003

Polyganics' Neurolac® bioresorbable nerve guide

neurium and back through the tube from the inside to the outside, after which a fie is made (Fig. 1.1-1.3).

When positioning optimization of the nerve ends in the nerve guide is required, it is recommended to place a second su-

Pull the proximal nerve stump into the nerve guide.

NOTE: It is recommended that the nerve ends are pulled into

ture in the same nerve end (Fig. 1.4).

the tube for at least 3 mm for optimal nerve regenera-



utilizing standard hospital procedures and universal precautions for bio-hazardous waste.



Catalog number 뿗

solution

For one use only

Lot number

FOI

Fill any remaining space with heparinized saline (Fig 1.6) by injecting along the nerve into the tumen of the tube or by

penetrating the tube (not the nerve)

Subsequently, use the same procedure, to pull the distal A minimum space of 5 mm should be left between the nerve

nerve stump into the nerve guide.

ends in the nerve guide.

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containing 1000 units of heparin per 100 ml of normal saline

saline

with heparinized

the tube (Fig 1.5). Ē

vci

Sterile product

STERILE

3-5 mm

Sterilized by ethylene oxide 11 STERILE | EO

Telephone Fax Polyganics BV L.J. Zielstraweg 1 9713 GX Groningen

Neurolac®- tube Proximal nerve-stump

The Netherlands

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Neurolac® is a registered trademark of Polyganics

lumen since this may hinder nerve recovery.

CAUTON: The nerve guide should be implanted and sutured
with all joints in an extended position as to assure that
no tension occurs on the proximal or distal nerve end

when joints are being mobilized.

CAUTION: Ensure that no blood enters the nerve guide

Figure 1. Schematic representation of suture technique for

suturing the nerve ends into the nerve guide

Proximal nerve-stump

Distal nerve-stump

À

Neurolac[®]. tube

© Polyganics BV, 2003

Close the wound and splint to prevent kinking for the first three postoperative weeks. Longlerm compression of the nerve guide should be avoided. Patients may be administered oral antibiotics for the first post-operative week.

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Version 19, 23-Jun-2003

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APPENDIX D: PREDICATE DEVICE NEUROTUBE™

Neuroregen L.L.C.

510(k): K983007

K983007

3/22/99

PREMARKET NOTIFICATION [510(K)] SUMMARY (as required by 21CFR 807.92(a))

Submitted by: John E. Barham, Managing Member, Neuroregen L.L.C.

43 N. Bond Street, Bel Air, MD 21014 Phone 410 838-8090 Fax 410 838-8092

Date:

August 28, 1998

Trade Name:

Neurotubetm

Common Name:

Nerve Conduit

Classification Name: Nerve Cuff (per 21 CFR Section 882.5275)

Equivalent Device.

Silicone Nerve Cuffs

Description: The Neurotube is a woven, flexible, polyglycolic acid tube which has been heat treated to achieve a configuration corrugated externally for wall strength. The tube is 2.3 mm in diameter and 4 cm in length.

Intended Use: The tube provides an optimal environment for longitudinal nerve axon growth of the peripheral nerve. For single use only in patients with a peripheral nerve injury where the nerve gap is more than or equal to 8 mm, but less than or equal to 3 cm.

Technological Characteristics Compared to Predicate Device: The Neurotube is fabricated from a bioresorbable material in contrast to nonresorbable silicone and thus precludes the need for a second surgery. Both the silicone and bioresorbable products are tubular in design to facilitate nerve regeneration.

Clinical Data: Clinical trials for the Neurotube were conducted in the United States over a period of three and one half years to support a determination of substantial equivalence.. A total of 98 subjects were enrolled at five clinical trial sites. One hundred two nerve reconstructions were evaluated. There were 56 in the control group using classic end-to-end nerve graft repairs and 46 received the Neurotube. Subjects were given sensory evaluations at 3, 6, 9, and 12 month intervals. Static and moving sensory discrimination tests were performed. Results were equivalent between the two groups. The only adverse effects reported were delayed healing of a skin closure and skin separation with partial extrusion of the Neurotube. The study indicated that a single stage, biodegradable, polyglycolic acid conduit can be used as an alternative to a nerve graft or a biodurable nerve tube.





Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

MAR 2 2 1999

Mr. John E. Barham Managing Member Neuroregen, L.L.C. 43 North Bond Street Bel Air, Maryland 21014

Re: K983007

> Trade Name: NeurotubeTM Regulatory Class: II Product Code: JXI

Dated: December 18, 1998

Received: December 22, 1998

Dear Mr. Barham:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. John E. Barham

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.

Director

Division of General and Restorative Devices Office of Device Evaluation Center for Devices and

Radiological Health

Enclosure

510 (k) Number <u>K983007</u>
Device Name: Neurotube™
Indications for Use:
The Neurotube is intended for single use in patients with an injury to a peripheral nerve, in which the nerve gap is more than or equal to 8 mm but less than or equal to 3 cm. The nerve gap may be created primarily at the time of injury or created secondarily at the time of exploration of failed primary repair.
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CRF 801,109) (Division Sign-Off) Division of General Restorative Davises (483007)

NeuroGen[™] Nerve Guide

JUN 2 2 2001

510(K) SUMMARY

Submitter's name and address:

Integra LifeSciences Corporation 105 Morgan Lane Plainsboro, NJ 08536 USA

Contact person and telephone number:

Judith E. O'Grady Senior Vice President, Regulatory Affairs, Quality Assurance and Clinical Research (609) 275-0500

Date Summary was prepared:

April 16, 2001

Name of the device:

Proprietary Name: NeuroGen™
Common Name: Nerve Guide

Classification Name: Nerve Cuff, Product Code 84JXI

Substantial Equivalence:

NeuroGen[™] Nerve Guide is substantially equivalent in function and intended use to the following products which have been cleared to market under Premarket Notifications 510(k): Salumedica Merve Cuff, NeuroTube and Fastube Nerve Cuff.

Device Description:

NeuroGen[™] Nerve Guide is an implant designed for repair of peripheral nerve discontinuities. NeuroGen[™] Nerve Guide provides a protective environment for peripheral nerve repair after injury. NeuroGen[™] Nerve Guide is designed to be an interface between the nerve and surrounding tissue and to create a conduit for axonal growth across a nerve gap.

NeuroGen[™] Nerve Guide is flexible to accommodate movement of joint and associated tendons while retaining its shape and is resistant to occlusive forces from surrounding tissue. When hydrated, NeuroGen[™] is an easy to handle, soft, pliable, nonfriable, porous collagen tube. NeuroGen[™] Nerve Guides are provided sterile in double blister packages in a variety of sizes.

Intended Use:

NeuroGen[™] Nerve Guide is indicated for repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity.

Safety

Biocompatibility studies have demonstrated NeuroGenTM Nerve Guides to be: noncytotoxic, nonpyrogenic, nonirritating, and nonsensitizing. The following studies were conducted:

- a) Cytotoxicity
- b) Irritation / Intracutaneous Reactivity
- c) Sensitization
- d) Acute Systemic Toxicity
- e) Subchronic Toxicity
- f) Chronic Toxicity
- g) Genotoxicity
- h) Implantation
- i) Hemolysis

Performance Characteristics:

The effectiveness of NeuroGen[™] Nerve Guide to repair peripheral nerve discontinuities was studied in a long-term (3.5 years) primate study and in rodent animal models. The studies demonstrated that NeuroGen[™] Nerve Guides are substantially equivalent to nerve graft, direct suture and silicone tubes.

The mechanical and physical characteristics of the NeuroGenTM Nerve Guides were evaluated in a series of tests. These tests were conducted to ensure that the NeuroGenTM Nerve Guides possess the mechanical properties (suture retention and mechanical compression) as well as physical properties (porosity and permeability) that determine their suitability for use in the human body. Testing has demonstrated that the nerve guides are able to hold a suture, resist repeated compression from surrounding tissues, have a porous outer surface and tube wall, and allow the passage of molecules of specific size through the tube wall.

Technological Characteristics Compared to Predicate Devices:

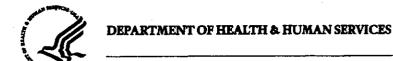
NeuroGen[™] Nerve Guide is a tubular device which is equivalent to the predicate devices, Salumedica[™] Nerve Cuff, NeuroTube[®] and Fastube[™] Nerve Cuff in its design for repair of peripheral nerve discontinuities. Like the predicate devices, NeuroGen[™] is provided sterile, for single use only. The NeuroGen[™] Nerve Guide is manufactured from a bioresorbable material, as is one of the predicate devices, NeuroTube[®]. NeuroGen[™] Nerve Guide meets ISO 10993 requirements for Biocompatibility testing.

Conclusion

NeuroGen[™] Nerve Guide is indicated for the repair of nerve discontinuities where gap closure can be achieved by flexion of the extremity. NeuroGen[™] Nerve Guide is flexible to accommodate movement of joint and associated tendons while retaining its shape and is resistant to occlusive forces from surrounding tissue.

Biocompatibility studies have demonstrated NeuroGen[™] Nerve Guide to be non-cytotoxic, non-sensitizing, non-toxic and non-mutagenic. Extensive, long-term evaluations in primates demonstrates NeuroGen[™] Nerve Guide to biocompatible and provides an environment for axonal growth.

Valid scientific evidence through substantial testing of descriptive characteristics, Biocompatibility, mechanical and physical property testing and extensive performance testing in a primate model, provide reasonable assurance that NeuroGen[™] Nerve Guide is safe and effective under the proposed conditions of use, and substantially equivalent to its predicate devices.



JUN 2 2 2001

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Ms. Judith E. O'Grady, RN, MSN
Senior Vice President, Regulatory Affairs,
Quality Assurance and Clinical Affairs
Integra Life Sciences Corporation
105 Morgan Lane
Plainsboro, New Jersey 08536

Re: K011168

Trade/Device Name: NeuroGen Nerve Guide

Regulation Number: 882.5275

Regulatory Class: II Product Code: JXI Dated: April 16, 2001 Received: April 17, 2001

Dear Ms. O'Grady:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Ms. Judith E. O'Grady, RN, MSN

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and Neurological Devices Office of Device Evaluation Center for Devices and Radiological Health

Enclosure

510(k) Number:

K011168

Device Name: NeuroGen™ Nerve Guide

Indications for Use

NeuroGen[™] Nerve Guide is indicated for repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity.

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

(Concurrence of	CDRH, Office of Device Evaluation (ODE)
Prescription Use X (Per 21 CFR 801.109)	OR Over-the-Counter Use
	(Division Sign-Off) Division of General, Restorative
	(Division Sign-Off)
	and Neurological Devices
	510(k) Number

E-0001



APPENDIX E: PREDICATE DEVICE NEUROGEN™

Integra Life Sciences Corporation

510(k): K011168

NeuroGen[™] Nerve Guide

JUN 2 2 2001

510(K) SUMMARY

Submitter's name and address:

Integra LifeSciences Corporation 105 Morgan Lane Plainsboro, NJ 08536 USA

Contact person and telephone number:

Judith E. O'Grady Senior Vice President, Regulatory Affairs, Quality Assurance and Clinical Research (609) 275-0500

Date Summary was prepared:

April 16, 2001

Name of the device:

Proprietary Name:

NeuroGen[™]

Common Name:

Nerve Guide

Classification Name:

Nerve Cuff, Product Code 84JXI

Substantial Equivalence:

NeuroGen[™] Nerve Guide is substantially equivalent in function and intended use to the following products which have been cleared to market under Premarket Notifications 510(k): Salumedica [™] Nerve Cuff, NeuroTube[®] and Fastube [™] Nerve Cuff.

Device Description:

NeuroGen[™] Nerve Guide is an implant designed for repair of peripheral nerve discontinuities. NeuroGen[™] Nerve Guide provides a protective environment for peripheral nerve repair after injury. NeuroGen[™] Nerve Guide is designed to be an interface between the nerve and surrounding tissue and to create a conduit for axonal growth across a nerve gap.

NeuroGenTM Nerve Guide is flexible to accommodate movement of joint and associated tendons while retaining its shape and is resistant to occlusive forces from surrounding tissue. When hydrated, NeuroGenTM is an easy to handle, soft, pliable, nonfriable, porous collagen tube. NeuroGenTM Nerve Guides are provided sterile in double blister packages in a variety of sizes.

Intended Use:

NeuroGenTM Nerve Guide is indicated for repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity.

D0001

Safety

Biocompatibility studies have demonstrated NeuroGen[™] Nerve Guides to be: noncytotoxic, nonpyrogenic, nonirritating, and nonsensitizing. The following studies were conducted:

- a) Cytotoxicity
- b) Irritation / Intracutaneous Reactivity
- c) Sensitization
- d) Acute Systemic Toxicity
- e) Subchronic Toxicity
- f) Chronic Toxicity
- g) Genotoxicity
- h) Implantation
- i) Hemolysis

Performance Characteristics:

The effectiveness of NeuroGen[™] Nerve Guide to repair peripheral nerve discontinuities was studied in a long-term (3.5 years) primate study and in rodent animal models. The studies demonstrated that NeuroGen[™] Nerve Guides are substantially equivalent to nerve graft, direct suture and silicone tubes.

The mechanical and physical characteristics of the NeuroGenTM Nerve Guides were evaluated in a series of tests. These tests were conducted to ensure that the NeuroGenTM Nerve Guides possess the mechanical properties (suture retention and mechanical compression) as well as physical properties (porosity and permeability) that determine their suitability for use in the human body. Testing has demonstrated that the nerve guides are able to hold a suture, resist repeated compression from surrounding tissues, have a porous outer surface and tube wall, and allow the passage of molecules of specific size through the tube wall.

Technological Characteristics Compared to Predicate Devices:

NeuroGen[™] Nerve Guide is a tubular device which is equivalent to the predicate devices, Salumedica[™] Nerve Cuff, NeuroTube[®] and Fastube[™] Nerve Cuff in its design for repair of peripheral nerve discontinuities. Like the predicate devices, NeuroGen[™] is provided sterile, for single use only. The NeuroGen[™] Nerve Guide is manufactured from a bioresorbable material, as is one of the predicate devices, NeuroTube[®]. NeuroGen[™] Nerve Guide meets ISO 10993 requirements for Biocompatibility testing.

Conclusion

NeuroGenTM Nerve Guide is indicated for the repair of nerve discontinuities where gap closure can be achieved by flexion of the extremity. NeuroGenTM Nerve Guide is flexible to accommodate movement of joint and associated tendons while retaining its shape and is resistant to occlusive forces from surrounding tissue.

Biocompatibility studies have demonstrated NeuroGen[™] Nerve Guide to be non-cytotoxic, non-sensitizing, non-toxic and non-mutagenic. Extensive, long-term evaluations in primates demonstrates NeuroGen[™] Nerve Guide to biocompatible and provides an environment for axonal growth.

Valid scientific evidence through substantial testing of descriptive characteristics, Biocompatibility, mechanical and physical property testing and extensive performance testing in a primate model, provide reasonable assurance that NeuroGen[™] Nerve Guide is safe and effective under the proposed conditions of use, and substantially equivalent to its predicate devices.



JUN 2 2 2001

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20650

Ms. Judith E. O'Grady, RN, MSN
Senior Vice President, Regulatory Affairs,
Quality Assurance and Clinical Affairs
Integra Life Sciences Corporation
105 Morgan Lane
Plainsboro, New Jersey 08536

Re: K011168

Trade/Device Name: NeuroGen Nerve Guide

Regulation Number: 882.5275

Regulatory Class: II Product Code: JXI Dated: April 16, 2001 Received: April 17, 2001

Dear Ms. O'Grady:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Ms. Judith E. O'Grady, RN, MSN

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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Sincerely yours,

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and Neurological Devices Office of Device Evaluation Center for Devices and Radiological Health

Enclosure

510(k) Number:

K011168

Device Name: NeuroGen™ Nerve Guide

Indications for Use

NeuroGen[™] Nerve Guide is indicated for repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity.

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

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APPENDIX F: PERFORMANCE TEST REPORTS

Suture retention testing
In vitro degradation testing
Nerve function recovery: sciatic nerve model
Neurolac nerve guide versus autologous nerve graft
Functional nerve recovery after bridging a 15 mm nerve gap with a Neurolac nerve guide



Suture retention testing



Research Report

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In vitro degradation testing



INTERIM RESEARCH REPORT

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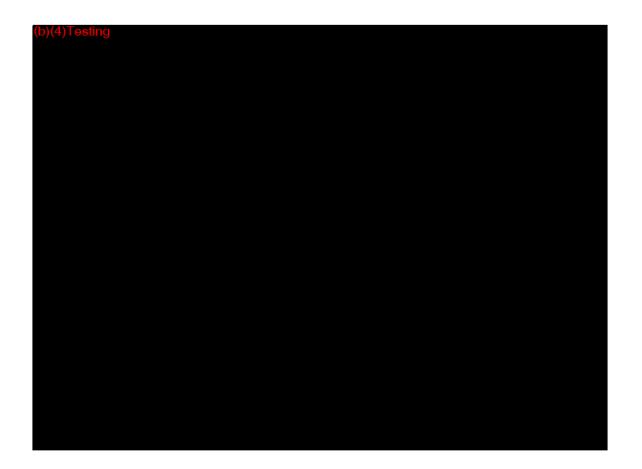


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Nerve function recovery: sciatic nerve model





RESEARCH REPORT

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Neurolac nerve guide versus autologous nerve graft



RESEARCH REPORT

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Functional nerve recovery after bridging a 15 mm nerve gap with a Neurolac nerve guide



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APPENDIX G: BIOCOMPATIBILITY DATA

Cytotoxicity
Irritation
Sensitization
Hemocompatibility
Acute systemic toxicity
Pyrogenicity
Mutagenicity /genotoxicity
Sub chronic toxicity
Carcinogenicity
Chronic toxicity
Reproductive toxicity
Implantation



Cytotoxicity

























Irritation































Sensitization









































































Hemocompatibility









































Acute systemic toxicity

















































Pyrogenicity



























Mutagenicity /genotoxicity



































































































Sub chronic toxicity





























Carcinogenicity

Chronic toxicity

Reproductive toxicity



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Study summary



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Implantation



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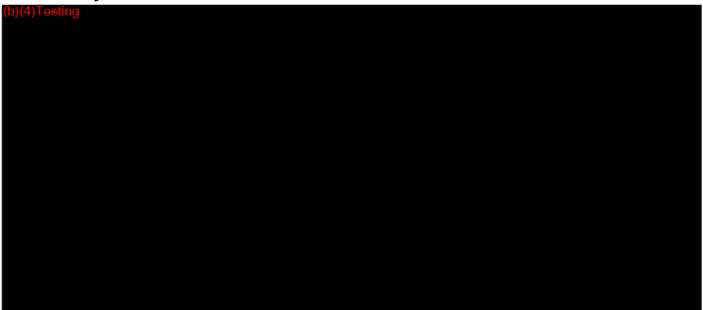
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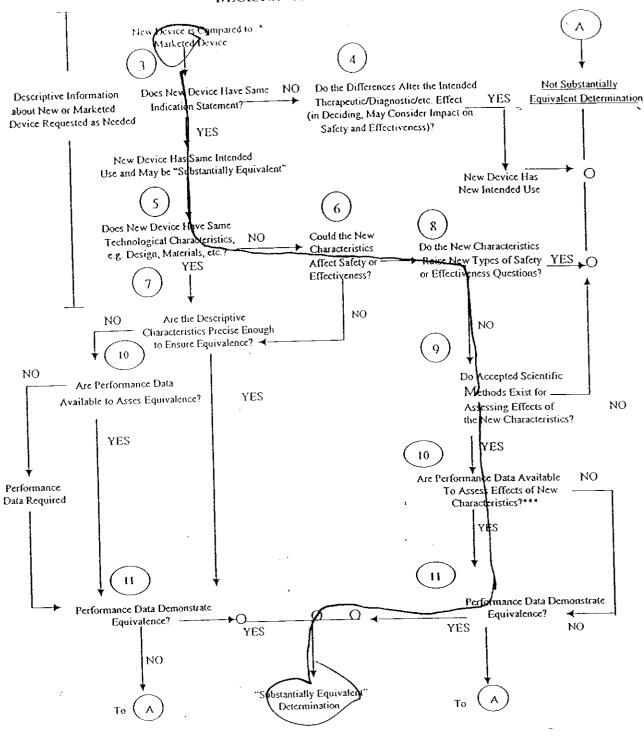
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- DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

	The Start with with	
From:	Reviewer(s) - Name(s) David R. Berkowitz put	
Subject:	510(k) Number	
To:	The Record - It is my recommendation that the subject 510(k) Notification:	-
[[Refused to accept. Requires additional information (other than refuse to accept). Sts substantially equivalent to marketed devices. NOT substantially equivalent to marketed devices. Other (e.g., exempt by regulation, not a device, duplicate, etc.)	
	Is this device subject to Section 522 Postmarket Surveillance? Is this device subject to the Tracking Regulation? Was clinical data necessary to support the review of this 510(k)? Is this a prescription device? Was this 510(k) reviewed by a Third Party? Special 510(k)? Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	
	Truthful and Accurate Statement Requested Enclosed A 510(k) summary OR A 510(k) statement The required certification and summary for class III devices The indication for use form	
	Combination Product Category (Please see algorithm on H drive 510k/Boilers)	1 🔯
□N	The submitter requests under 21 CFR 807.95 (doesn't apply for SEs): No Confidentiality	eding 90
Pred	icate Product Code with class: Additional Product Code(s) with panel (optional	l):
ZXI_	Review: (Branch Chief) Review: (Branch Chief) Final Review: Muram C. Provost (Date) (Date)	
Davicad-ADIC	(Division Director)	١

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



⁵¹⁰⁽k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

^{→ → →} Data maybe in the \$10(k), other \$10(k)s, the Center's classification files, or the literature.

510(K) MEMORANDUM

TO: K032115

FROM: David B. Berkowitz, Veterinarian

ODE/DGRND/Plastic and Reconstructive Surgery Devices Branch

DATE: October 7, 2003

SUBJ: Neurolac® Nerve Guide

Polyganics BV

Jan Bart Hak, Manager of clinical and Regulatory Affairs (See Aug. 4, letter)

31 50 588 6588

Recommendation: S.E.

Procode: JXI Class: II

Regulation Number: 882.5275

Regulation Name: Nerve Cuff

REVIEW:

Device Description: This is a co-polyester of poly(DL-lactide-ε-caprolactone) tube used to guide regenerating axons and to exclude ingrowth of fibrous tissue during regeneration.

1. <u>Comparison of the Intended Use/Indications of the Subject Device and Predicate(s)</u> Subject Device

For the reconstruction of a peripheral nerve discontinuity up to 20mm in patients who have sustained a complete division of a nerve.

Predicate devices

K983007 Neurotube Neuroregen LLC For single use in patients with a peripheral nerve injury where the nerve gap is more than or equal to 8 mm, but less than 3 cm. The tube is made of polyglycolic acid.

K011168 NeuroGen[™] Nerve Guide – For the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity. The tube is made of bovine collagen.

Discussion of whether the intended use/indications are the same

The K011168 closure is limited to cases in which closure can be achieved by flexion. The current device is not restricted to flexion. I do not know the significance of this restriction. The current device can be used for up to a 20 mm gap, well within the range of the predicates.

2. <u>Comparison of the Technological Characteristics (Design, Materials, Sizes, Shapes, etc.)</u> of the Subject Device and Predicate(s) Subject Device

The chemical composition is provided. This is a copolyester of poly(DL-lactide-ε-caprolactone) tube. The tube retains strength for 8 weeks, and then rapidly degrades. (b) (4)

Predicate Devices

K983007 Neurotube™ Nerve Cuff – Made from polyglycolic acid. 2.3 mm diameter and 4 cm long. Full absorption in 6 months. The corrugated configuration said to prevent collapse of tube from soft tissue pressure.

K0111168 – Made from bovine collagen. 2-4 cm, with i.d. 2, 4, 5, 6, and 7 mm.

Discussion of whether the subject device has a significant change in technological characteristics.

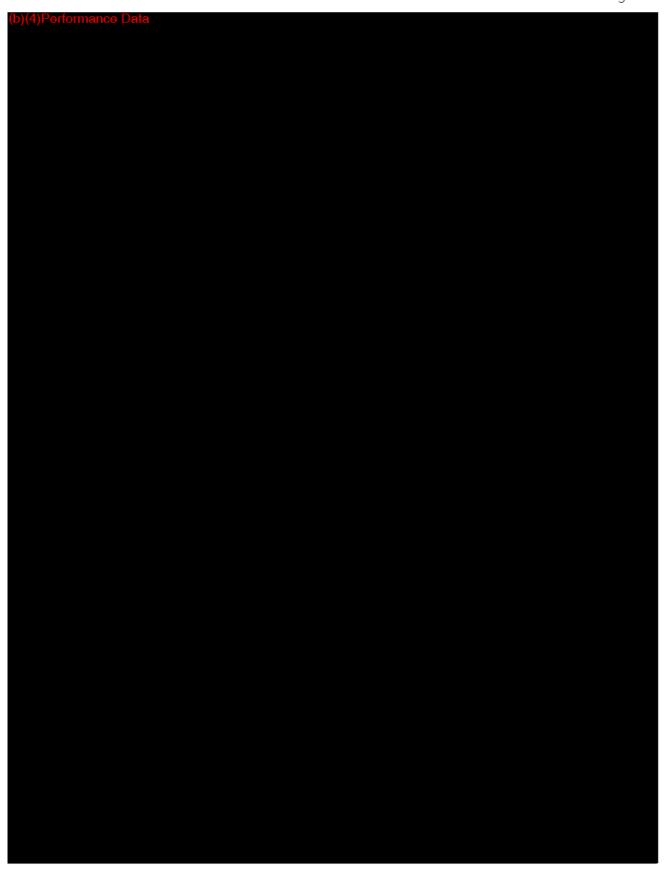
The materials are different for each device. Other predicates include silicone and collagen tubes. Equivalence rests on the safety and effectiveness similarities.

3. Comparative Data (in vitro, animal and/or clinical) Safety Data - Subject Device



(b)(4)Performance Data	3

(b)(4)Performance Data	
Safety Data - Predicate Devices	
(b)(4)Performance Data	
(b)(4)) enomance Data	
Effectiveness Data – Subject Device	
(b)(4)Performance Data	



Ef	ectiveness Data - Predic nnco Data	ate Devices		
ef	scussion of whether the ective as the predicate(s	data demonstrate tl)	hat the subject device	e is as safe and
rformance D	aia	<i>,</i>		

4. Does the product contain drugs or biologicals?

a. If yes, what drug(s)/biologic(s): No Combination Product Code: N

5. Sterilization



6. Is the Labeling Adequate?

(OTC and/or Prescription) Rx Package Insert (page) 17 and appendix C



7. Claims

b) (4)

8. Has sponsor provided all administrative requirements?

- Truthful and Accurate Statement 10
- 510(k) Summary or Statement 32
- Indication for Use Page 8

9. Analysis of the Equivalence of the Subject and Predicates

(b) (4)

10. Contact History/Requests for More Information:



David B Behout

10/8/03 Date

Plastic and Reconstructive Surgery Devices Branch

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND HUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

KO32115
Reviewer: David Berkow, 12
Division/Branch: DERNO (PRSIR
Device Name: Neurolac Nerve Guide
Product To Which Compared (510(K) Number If Known):

	·	YES	NO	
, -, , -	Dovice	1		If NO = Stop
	Is Product A Device	1		If NO = Stop
	Is Device Subject To 510(k)?	1		If YES = Go To 5
l .	Same Indication Statement?			If YES = Stop NE
1.	Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			·
 5.	Same Technological Characteristics?		V	If YES = Go To 7
6.	Could The New Characteristics Affect Safety Or Effectiveness?	V		If YES = Go To 8
7.	Descriptive Characteristics Precise Enough?			If NO = Go To 10 If YES = Stop SE
8.	New Types Of Safety Or Effectiveness Questions?		\ <u>\</u>	If YES = Stop N
	Accepted Scientific Methods Exist?	V		If NO = Stop NE
9.	Performance Data Available?	V		If NO = Request
11.	Data Demonstrate Equivalence?	\\\		Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

Obscurrently us to 20 mm in parents with a coupling herre dursus
Device Description: Provide a statement of how the device is either Intended Use: similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

- Explain why not a device: 1.
- Explain why not subject to 510(k): 2.
- How does the new indication differ from the predicate device's indication:
- Explain why there is or is not a new effect or safety or effectiveness 4. issue: The muteual is new furthis tapped clere!
- Describe the new technological characteristics:

 The during Marke from Poly Describe & Copyolarian,

 Explain how new characteristics could or could not affect safety or
- effectiveness: may inderfer with neural avantomersis 6.
- Explain how descriptive characteristics are not precise enough: 7.
- Explain new types of safety or effectiveness questions raised or why questions are not new:
- Explain why existing scientific methods can not be used: 9.
- Explain what performance data is needed:
- Explain how the performance data demonstrates that the device is or i not substantially equivalent:

Verform as well as fredical ATTACH ADDITIONAL SUPPORTING INFORMATION

Internal Administrative Form

	YES	
 Did the firm request expedited review? Did we grant expedited review? Have you verified that the Document is labeled Class III for GMP purposes? If, not, has POS been notified? Is the product a device? Is the device exempt from 510(k) by regulation or policy? 	X	
 Is the device exempt from 5. Is the device subject to review by CDRH? Is the device subject to review by CDRH? Are you aware that this device has been the subject of a previous NS decision? If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)? Are you aware of the submitter being the subject of an integrity investigation? If, yes, consult the ODE Integrity Officer. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991. 	E	

Berkowitz, David

From: Hak [hak@polyganics.com]

Sent: Wednesday, October 08, 2003 4:22 AM

To: Berkowitz, David

Subject: Re: 510(k) application

Dear Mr. Berkowitz,



Kind regards,

Jan-Bart Hak

---- Original Message ----- From: Berkowitz, David

To: 'Hak'

Sent: Tuesday, October 07, 2003 2:44 PM

Subject: RE: 510(k) application



-----Original Message-----

From: Hak [mailto:hak@polyganics.com] **Sent:** Friday, October 03, 2003 9:55 AM

To: Berkowitz, David **Subject:** Re: 510(k) application

Dear Mr. Berkowitz,





Kind regards,

Jan-Bart Hak, Ph.D. Manager Clinical and Regulatory Affairs Polyganics BV tel:+31 50 588 6586 gsm: +31 653 211 303

The above information is intended only for the person or entity to whom it is addressed and may contain confidential and/or priviledged information. Any review, retransmission, dessemination of, or taking action in reliance upon this information by others than the intended recipient is prohibited. If you are not the intended recipient, please return this e-mail to the sender and delete it from any computer system.

---- Original Message ----- From: Berkowitz, David

To: 'Hak'

Sent: Thursday, October 02, 2003 1:10 PM

Subject: RE: 510(k) application

(b) (4)

----Original Message----

From: Hak [mailto:hak@polyganics.com]
Sent: Thursday, October 02, 2003 2:46 AM

To: Berkowitz, David

Subject: Re: 510(k) application

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I think e-mail is a perfect to address any issue quickly. I looking forward to your questions.

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Jan-Bart Hak, Ph.D.

Manager Clinical and Regulatory Affairs Polyganics BV tel:+31 50 588 6586

Mobile: +31 653 211 303

----- Original Message ----From: Berkowitz, David
To: 'hak@polyganics.com'
Sent: Wednesday, October 01, 2003 7:22 PM
Subject: 510(k) application

Berkowitz, David

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Subject: 510(k) application

(b) (4)



			POLY	GANICS
Indications for Use	Form			
510(k) Number:				
Device Name:	Neurolac® Nerve G	Suide		
Indications for Use:				
The N discon nerve.	tinuity up to 20 mm in	s indicated for the r n patients who have	reconstruction of a periple sustained a complete d	neral nerve livision of a
(PLEASE DO NOT NEEDED)	WRITE BELOW TH	HIS LINE - CON	TINUE ON ANOTHER	PAGE IF
Concurrence of CDR	H, Office of Device Ev	valuation (ODE)		
Prescription Use	OR	Over-The-Coun	nter Use	
(Per 21 CFR 801.109			Optional Format 1-2-96)	
	(Division Sign	n-Off)		
	510(k) Numbe	er		



510(k) **Summary of Safety and Effectiveness**

Submitter:

Polyganics BV L.J. Zielstraweg 1 9713 GX, Groningen The Netherlands www.polyganics.com

Jan Bart Hak, Ph.D.

Contact

Manager Clinical and Regulatory Affairs

Person:

Tel : +31 50 588 6588 : +31 50 588 6599 Mobile: +31 653 211 303 E-mail: hak@polyganics.com

Date

May 20, 2003

Prepared:

General Provisions:

Trade Name: Neurolac® Nerve guide

Common Name: Nerve guide

Classification Name: Nerve Cuff, 21 CFR 882.5275

Device Classification: Class II

Predicate Devices:

Neurotube™

Neuroregen L.L.C.

K983007

NeuroGen™

Integra Life Sciences Corp. K011168

Performance **Standards**

For the Nerve Cuff performance, the FDA, under section 514 of the Food, Drug and Cosmetic Act, has not established standards.

Indications for Use

The Neurolac® nerve guide is indicated for the reconstruction of a peripheral nerve discontinuity up to 20 mm in patients who have sustained a complete

division of a nerve.



Device Description

Neurolac® is designed to be a flexible and transparent resorbable poly(DL-lactide-co-ε-caprolactone) tube to provide a protective environment for peripheral nerve regeneration after injury and to create a conduit to guide axonal growth across a nerve gap.

Neurolac® nerve guides are provided sterile in Tyvek pouch packages and retainer in a variety of sizes.

Performance Data:

The safety and effectiveness of the Neurolac nerve guides have been demonstrated via data collected from design verification tests and analyses. The design verification testing consisted of the following:

- In vitro suture retention testing
- In vitro degradation testing
- In vivo nerve function recovery

Summary of Substantial Equivalence

The design, fundamental technology and intended use (safety and efficacy) featured with the Neurolac® Nerve Guide are substantially equivalent to those featured with the competitor devices Neurotube™ (ref. 510(k) 983007; Neuroregen L.L.C.) and the NeuroGen™ Nerve Guide (ref. 510(k) 011168; Integra Life Sciences Corporation).

Biocompatibility, mechanical and physical property testing, in vitro degradation testing, and performance testing in an animal model provide reasonable scientific evidence that Neurolac® nerve guide is substantially equivalent to the predicate devices. Evaluation of the Polyganics Neurolac® Nerve guide based on biocompatibility testing, animal tests, results from literature and the comparison of the Neurolac® nerve guide with its predicate devices, shows that the Neurolac® nerve guide is safe for implantation.



Section 3: PROPOSED LABELING

Subject Device Labeling

The following proposed labeling for the subject device Neurolac Nerve Guide is provided in APPENDIX C:

- Outer label (Carton)
- Inner label (Pouch)
- Pre-printed carton text and graphics
- Instructions for Use

Intended Use of the Subject Device

The Neurolac nerve guide is indicated for the reconstruction of a peripheral nerve discontinuity up to 20 mm in patients who have sustained a complete division of a nerve.

Promotional Materials

At present, no promotional materials are available for the subject device.

Polyganics' Neurofac® bioresorbable nerve guide

Instructions for Use, English

STERILE. Sterilized with ethylene oxide gas. For single use CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Neurolac® peripheral nerve guide

Description

copolyester poly(DL lagger or proposal) and copolyester poly(DL lagger or profession of guide provides guidance and profestion to regenerating axons. The Neurolac nerve guide elicits a minimal acute inflammatory reaction of the surrounding issue, which is followed by gradual encapsulation of the tube by filmous tissue. Degradation of the Neurolac nerve guide occurs through hydrolysis leading to gradual reduction of molecular weight. The Neurolac nerve guide retains its infall mechanical properties up to 8 weeks, whereafter repuit base of mechanical strength and gradual mass loss occur. The final degradation products, lette acid and o-hydroxy. The final degradation products, lactic acid and e-hydroxy hexanolic acid, are resorbed, metabolized and excreted by the body. Animal studies demonstrated that a Neurolac nerve guide The Neurolac nerve guide is composed of the bioresorbable s resorbed within 16 months.

The Neurolac nerve guide inner diameter is indicated on the label, and is packed in a tray placed in a Tyvek pouch. The Neurolac nerve guide is indicated for single-use.

Indications

The Neurolac nerve guide is indicated for the reconstruction of a peripheral nerve discontinuity up to 20 mm in patients who have sustained a complete division of a nerve.

Contraindications

NOTE က် 4 'n.

extrusion of intra-fascicular components. Measure the length of the defect with all joints in an

If the gap length is between 0 and 20 mm, the injured nerve can be reconstructed with a Neurolac nerve guide. Select the Neurolac nerve guide with the proper internal

NOTE: It is essential that the internal nerve guide diameter is slightly larger than the diameter of the transected nerve to dightly larger than the expensation.

5. Out the selected nerve guide with a pair of scissors or a knife so that the nerve guide is 1 cm longer than the nerve

There are no known contraindications.

Warnings

- The Neurolac nerve guide is for single use only. Do not restentize or re-use. Structural integrity and/or function may be impaired through cleaning, resterflization, or re-use and
- may cause adverse patient reactions. Accordingly, Polyganics B V will not be responsible for any direct or consequential damages or expenses resulting from re-use of (or any part of) the Neurolac nerve guide:
 Stenie unless package has been opened or damaged. Discard open unused nerve guide should only be used by physicians who are trained in nerve defect repair techniques. Accordingly, Polyganics BV will not be responsible for any direct or consequential damages or expenses resulting from use by untrained personnel. The physician should constituent recent iterature on current medical products. practice on peripheral nerve repair;

Under some circumstances immobilization of the nerve ends, as to avoid trainen on this rainer ends, may be employed at the discretion of the surgeon. To secure adequate fixation of the nerve ends, the prevent and the accepted surgical technique of flat, square hes with additional throws as warranted by surgical circumstance and the experience of the surgical circumstance and the experience of the surgical circumstance and the experience of the surgical.

Narve regeneration may be suboptimal in elderly, malhourished or debilated patients or in patients suffering from cancer, namenia, obesity, diabetes, infection or other conditions which may delay wound healing, infected wounds, or moderate tissue inflammatory response characteristic of foreign body response.

S.

Precautions

- Use prior to "Use by date";
- Store in dark, dry place at or below 4°C (39°F);

 Do not expose the nerve guide to organic solvents (e.g. chloroform, acetone);
 - Do not use absorbable sutures for fixation of the nerve stumps into the nerve guide,
- Page 1 © Polyganics BV, 2003

Version 21 US, 08-Oct-2003

Polyganics' Neurolac® bioresorbable nerve guide

POLYGANICS

Avoid crushing, crimping, kinking or other damage due to application of surgical instruments such as forceps, needle-

POLYGANICS

accompanying

NOTE: It is recommended that the nerve ends are pulled into the tube for at least 3 mm for optimal nerve

(Fig 1.5). Subsequently, use the same procedure, to pull the distal Fill the tube with heparinized saline, using a solution containing 1000 units of heparin per 100 ml of normal saline regeneration. Fill the tube

splint

Prevent compression and/or kinking of the Neurolac the procedure. The use of a protective splir holders and scissors or during handling of the device. Avoid tension on the nerve ends:

ecommended

Adverse effects

- A minimum space of 5 mm should be left between the nerve nerve stump into the nerve guide. 7 ö
- ends in the nerve guide. Fill any remaining space with heparinized saline (Fig 1.6) by injecting along the nerve into the lumen of the tube or by penetrating the tube (not the nerve).

Adverse events associated with the use of a Neurolac nerve guide may include but are not limited to:

Fallure to provide adequate nerve regeneration at sites

Failure to provide adequate/complete nerve regeneration;

Transitory local irritation; Infection: Delayed wound healing. Opening of the package

Allergy;

where too much tension or compression occurs;



Neurolac[®], tube Proximal nerve-stunp

m

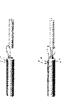
Surgically expose the injured nerve. Resect the injured segment distally and proximally until a nerve stump is identified with no residual intrafascicular Do not crush the nerve stumps as this can cause

~

The pouch is opened in such a way that the tray remains sterile. The tray sca be opened by sliding the lid. By classing the nerve guide at one of its ends between a pair of tweezers, it can be taken from the tray. The lid contains a ruler that may be used as a

reference to estimate the gap length or nerve stump diameter.

Surgical Procedure





S

Proximal nerve-stump ωà Distal nerve-stump

Figure 1. Schematic representation of suture technique for suturing the nerve ends into the nerve guide.

lumen since this may hinder nerve recovery.

CAUTON: The nerve guide should be implanted and sutured with all joints in an extended position as to assure that no tension occurs on the proximal or distal nerve end CAUTION: Ensure that no blood enters the nerve guide when joints are being mobilized Close the wound and splint to prevent kinking for the first first breakers. Long-term compression of the merve guide should be avoided. Patients may be administered oral antibiotics for the first post-operative

Suture the Neurolac nerve guide by passing the suture (8-0 suture) first through the tube from the outside to the inside and then transversally and superficially through the epineurum and back through the tube from the inside to the outside, after which a tie is made (Fig. 1.1-1.3).

When positioning optimization of the nerve ends in the nerve guide is required, it is recommended to place a second suture in the same nerve end (Fig. 1.4).

e

Pull the proximal nerve stump into the nerve guide.

Place the Neurolac nerve guide in warm safine (37°C) for approximately 1 minute before implantation. This will make the tube more flexible and ease needle passage during suturing.

Suturing Technique

Dispose contaminated implantation and packaging matenals utilizing standard hospital procedures and universal precautions for bio-hazardous waste.

+31 50 588 6588 +31 50 588 6599 Sterilized by ethylene oxide ese For single use only Telephone Fax Catalog number Refer to instructions for Sterile product Lot number Use by Polyganics BV L.J. Zielstraweg 1 9713 GX Groningen The Netherlands STERILE EO STERILE (\bowtie) D**4**

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