



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (kml)
FOLDER: K072076 - 395 pages
COMPANY: OSTEOGENICS BIOMEDICAL, INC. (OSTEBIOMA)
PRODUCT: SUTURE, SURGICAL, NONABSORBABLE, EXPANDED, POLYTETRAFLUROETHYLENE (NBY)
SUMMARY: Product: CYTOPLAST PTFE SUTURE

DATE REQUESTED: Nov 4, 2015

DATE PRINTED: Nov 4, 2015

Note: Printed





Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Osteogenics Biomedical, Inc.
% Mr. Dustyn Webb
Regulatory/Quality Manager
4620 71st Street, Building 78-79
Lubbock, Texas 79424

OCT 31 2007

Re: K072076

Trade/Device Name: Cytoplast PTFE Suture
Regulation Number: 21 CFR 878.5035
Regulation Name: Nonabsorbable expanded polytetrafluoroethylene surgical suture
Regulatory Class: II
Product Code: NBY
Dated: October 9, 2007
Received: October 9, 2007

Dear Mr. Webb:

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 Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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 – Mr. Dustyn Webb

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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K072076
p. 1 of 1

Indications for Use

510(k) Number (if known): K072076

Device Name: Cytoplast PTFE Suture

Indications For Use:

The Cytoplast® PTFE Suture is indicated for use in all types of soft tissue approximation and/or ligation, including cardiovascular, dental and general surgeries, as well as repair of the dura mater. The device is not indicated for use in ophthalmic surgery, microsurgery and peripheral neural tissue.

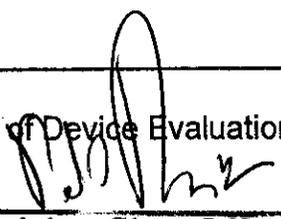
Prescription Use
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
 (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

Page 1 of 1

510(k) Number K072076



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Osteogenics Biomedical, Inc.
% Mr. Dustyn Webb
Regulatory/Quality Manager
4620 71st Street, Building 78-79
Lubbock, Texas 79424

OCT 31 2007

Re: K072076

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Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 28 2007

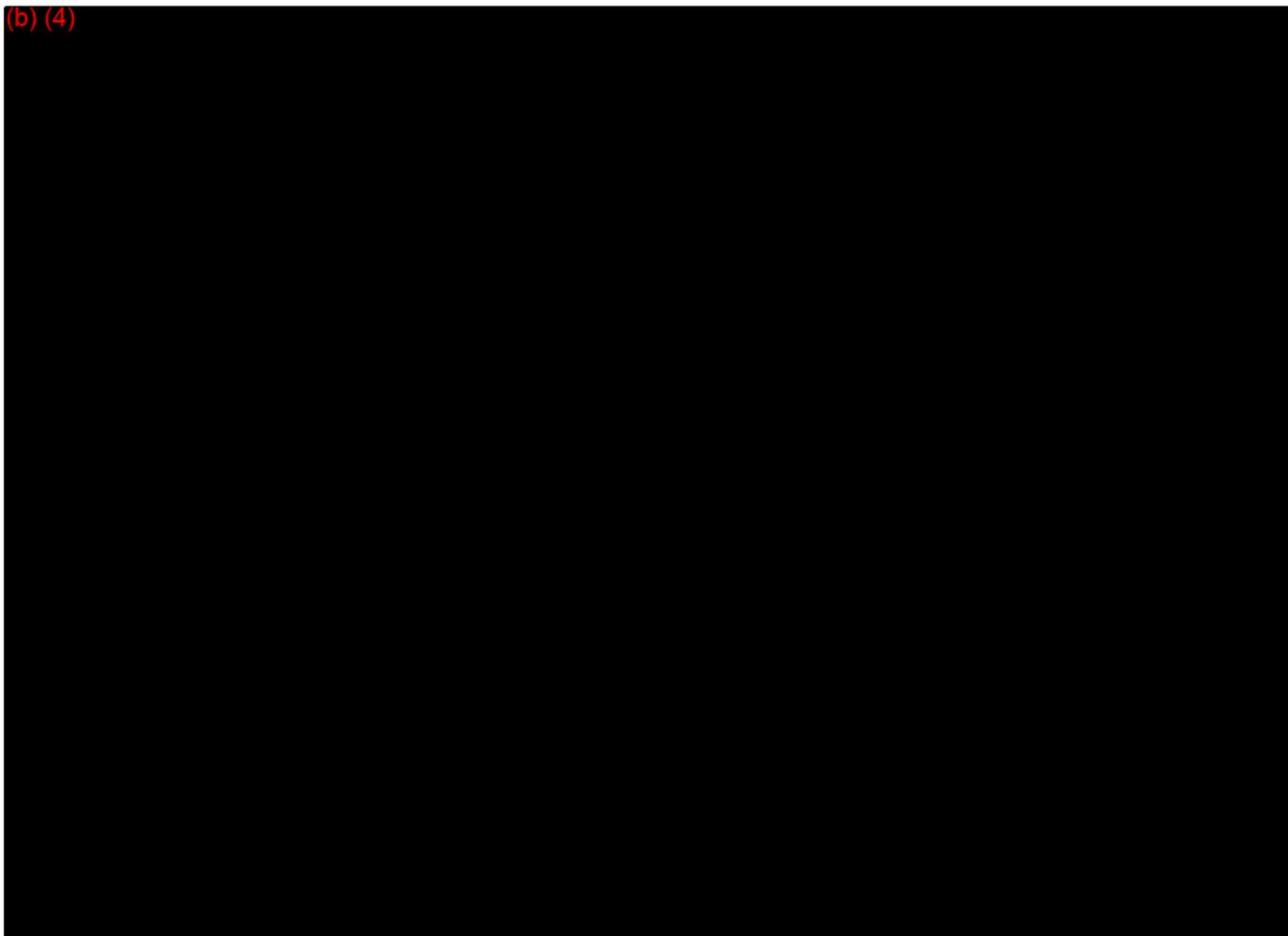
Osteogenics Biomedical, Inc.
% Mr. Dustyn Webb
Regulatory/Quality Manager
4620 71st Street, Building 78-79
Lubbock, Texas 79424

Re: K072076
Trade Name: Cytoplast PTFE Suture
Dated: July 25, 2007
Received: July 30, 2007

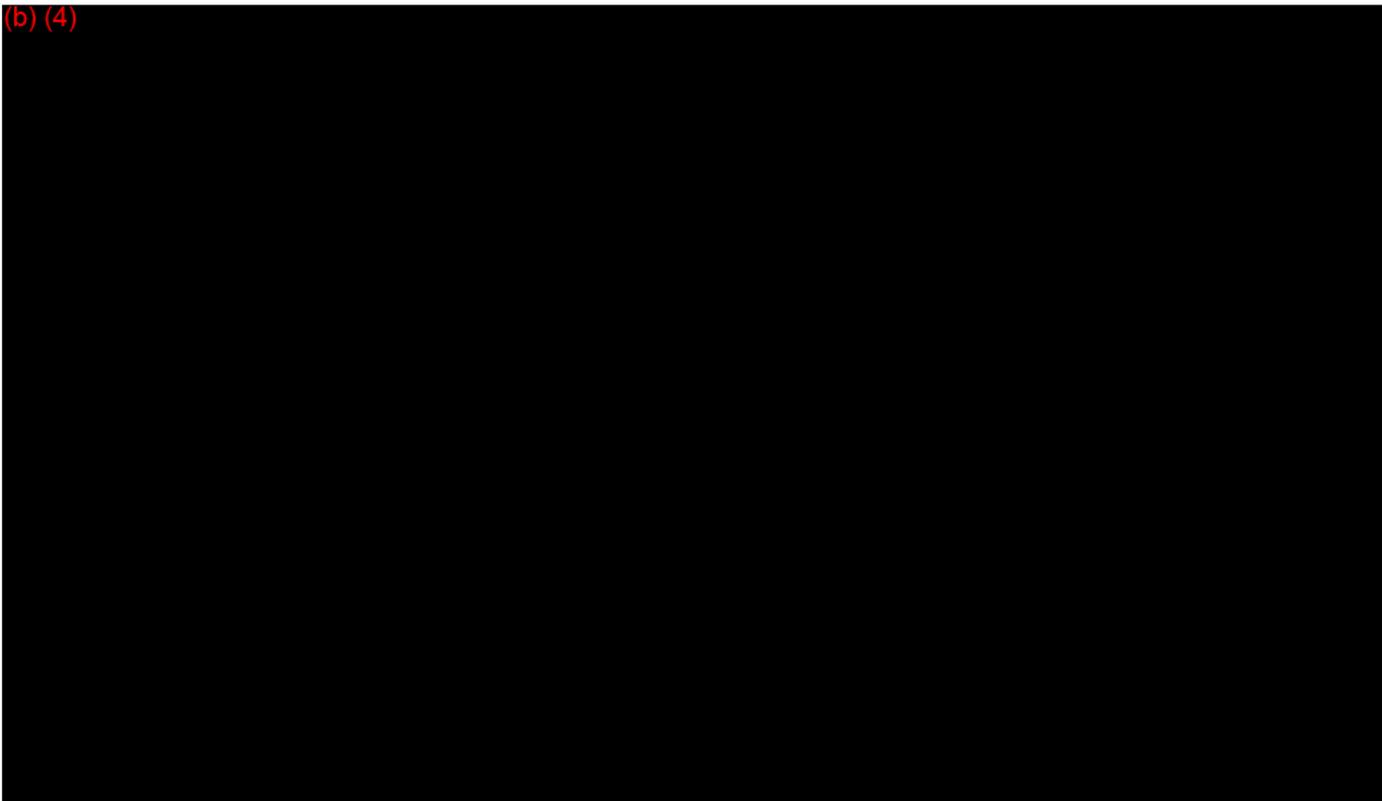
Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following information.

(b) (4)



(b) (4)



The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device.

We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. Please note our guidance document entitled, "Guidance for Industry and

Page 3 – Mr. Dustyn Webb

FDA Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment”. If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning the contents of the letter, please contact Lisa M. Lim, Ph.D. at (240) 276-3555. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (240) 276-3150, or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



for Mark N. Melkerson
Director
Division of General, Restorative
and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

(1) Indications for Use Form ODE Revised

SEP 28 2007

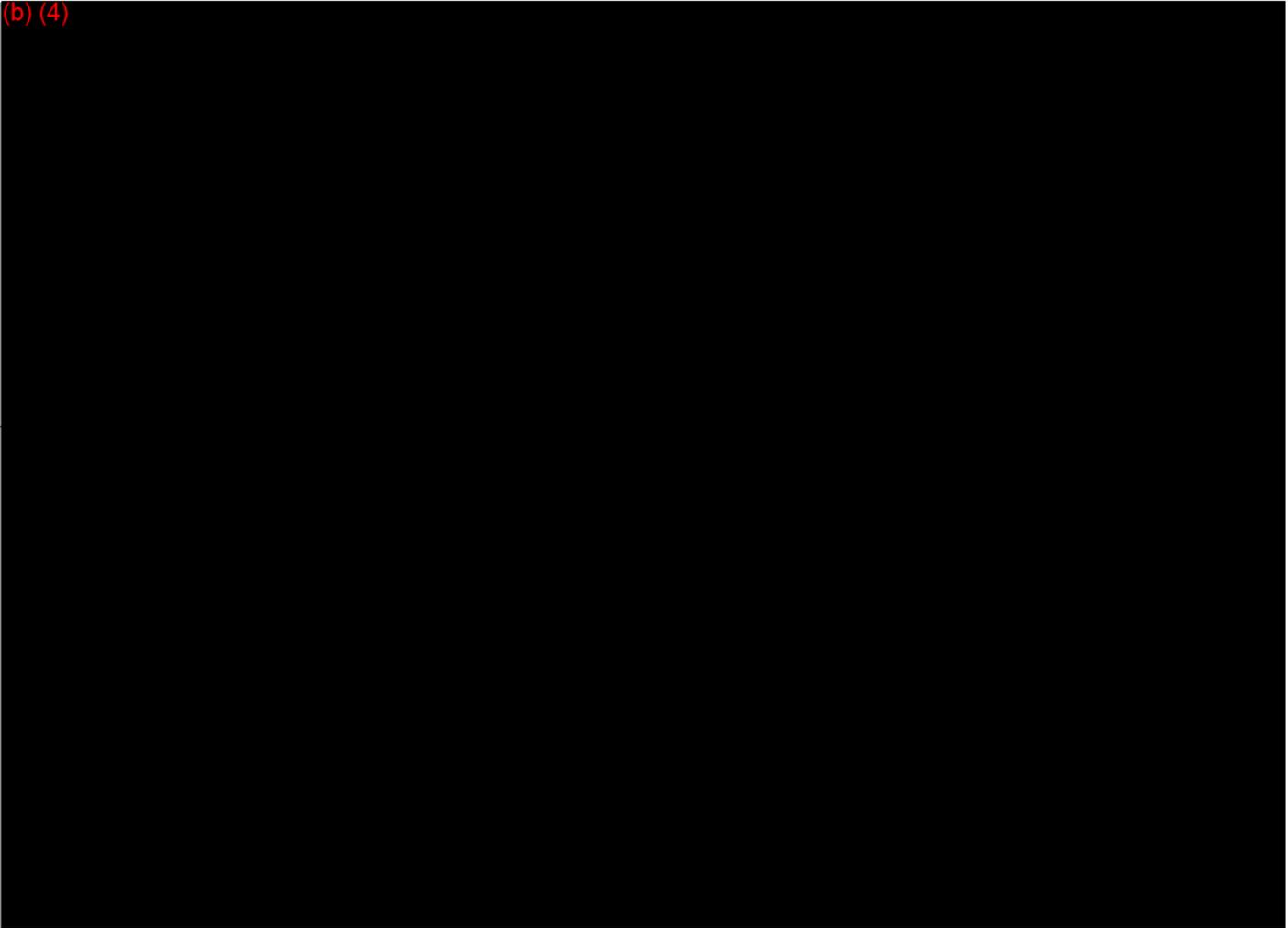
Osteogenics Biomedical, Inc.
% Mr. Dustyn Webb
Regulatory/Quality Manager
4620 71st Street, Building 78-79
Lubbock, Texas 79424

Re: K072076
Trade Name: Cytoplast PTFE Suture
Dated: July 25, 2007
Received: July 30, 2007

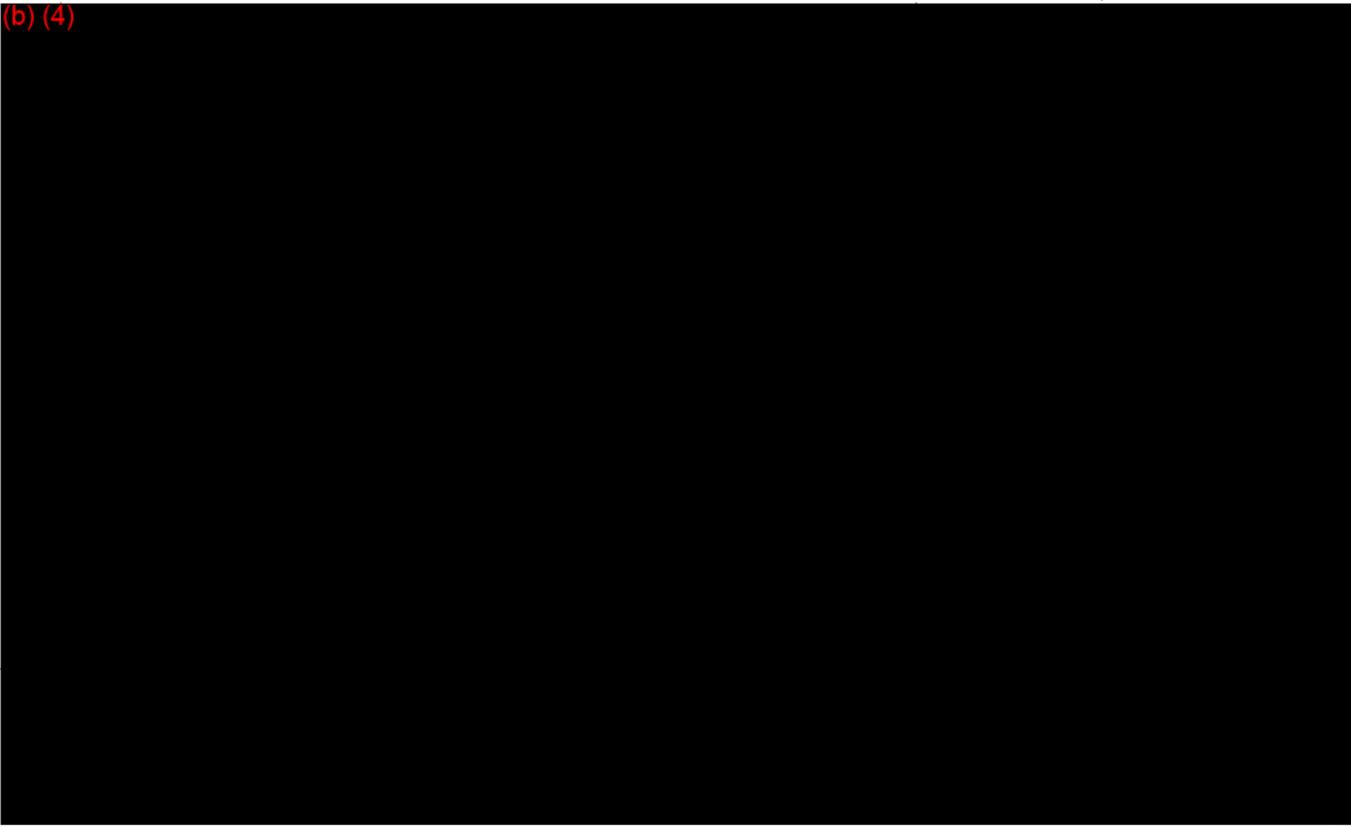
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Page 3 - Mr. Dustyn Webb

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Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
(1) Indications for Use Form ODE Revised

FILE
COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
2-110	[Signature]	3/29/13						
2-110	KNOX	3/28/13						

Page 4 – Mr. Dustyn Webb

cc: HFZ-401 (DMC - 2 copies: 1 copy of yellow sign-off & original)
HFZ-404 510(k) Staff
HFZ-410 DGRND
D.O.

LAODE\DGRND\PRSB\LML\K072076 – Let - AI.DOC

August 02, 2007

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

OSTEOGENICS BIOMEDICAL, INC.
4620 71ST ST., BLDG. 78-79
LUBBOCK, TX 79424
ATTN: DUSTYN WEBB

510(k) Number: K072076
Received: 31-JUL-2007
Product: CYTOPLAST PTFE
SUTURE

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) 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.**

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 510(k) submission.

Please note the following documents as they relate to 510(k) review:

- 1) Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act (MDUFMA). Please review this document at www.fda.gov/cdrh/mdufma/guidance/1219.html.
- 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).
- 3) 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.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsup.html.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/. If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsma/dsmastaf.html>. If you have procedural questions, please contact the 510(k) Staff at (240)276-4040.

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 30, 2007

OSTEOGENICS BIOMEDICAL, INC.
 4620 71ST ST., BLDG. 78-79
 LUBBOCK, TX 79424
 ATTN: DUSTYN WEBB

510(k) Number: K072076
 Received: 30-JUL-2007
 User Fee ID Number: 6031783
 Product: CYTOPLAST PTFE
 SUTURE

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 all 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. Please send a check to one of the addresses listed below:

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 be faxed to CDRH at (240)276-4025 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 www.fda.gov/oc/mdufma.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, or HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/electsub.html.

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 a 510k Submission with FDA or what type of submission to submit, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (240) 276-3150 or its toll-free number (800)638-2041, or contact them at their Internet address www.fda.gov/cdrh/dsma/dsmastaf.html, or you may submit a 513(g) request for information regarding classification to the Document Mail Center at the address above. If you have any questions concerning receipt of your payment, please contact Christina Zeender at Christina.Zeender@fda.hhs.gov. If you have questions regarding the status of your 510(k) Submission, please contact DSMICA at the numbers or address above.

Sincerely yours,

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

10072076

**Abbreviated 510(k)
Premarket Notification**

**Class II Special Controls Guidance Document:
Surgical Sutures; Guidance for Industry and FDA
June 3, 2003**

VOLUME 1

**Cytoplast[®] PTFE
Suture**

Osteogenics Biomedical, Inc.
4620 71st Street, Bldg 78-79
Lubbock, TX 79424

Submission Date: July 26, 2007

K22
SU
II

1	<u>Cover Sheets</u> <ul style="list-style-type: none"> • Medical Device User Fee • CDRH Premarket Review Submission
2	<u>Cover Letter</u> <ul style="list-style-type: none"> • 510(k) Cover Letter • Design & Use of the Device
3	<u>Statements</u> <ul style="list-style-type: none"> • 510(k) Statement • Truthful & Accuracy Statement
4	<u>Summary Report:</u> <u>Declaration of Conformity/Guidance Document</u> <ul style="list-style-type: none"> • Declaration of Conformity • Class II Special Controls: Surgical Sutures...
5	<u>Summary Report:</u> <u>Executive Summary/Risk Management</u> <ul style="list-style-type: none"> • 510(k) Executive Summary • Risk Management
6	<u>Summary Report:</u> <u>Descriptive Information</u> <ul style="list-style-type: none"> • Device Description/Actions • Product Picture • General Information
7	<u>Summary Report:</u> <u>Indications/Labeling</u> <ul style="list-style-type: none"> • Indications for Use • Sample-Instructions for Use • Samples-Box & Pouch Labels
8	<u>Summary Report:</u> <u>Comparative Information</u> <ul style="list-style-type: none"> • Statement of Equivalence • Comparative Information Table
9	<u>Summary Report:</u> <u>Sterilization/Shelf Life Information</u> <ul style="list-style-type: none"> • Sterilization/Shelf Life Statements
10	<u>Summary Report:</u> <u>Biocompatibility Information</u> <ul style="list-style-type: none"> • Statement of Equivalence • Cytotoxicity Study Report • Biocompatibility Summary

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER:

(b) (4)

Write the Payment Identification number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (Note: In no case should payment be submitted with the application.)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 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.)
For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: <http://www.fda.gov/cdrh/mdufma/faqs.html#3a>. You are responsible for paying all fees associated with wire transfer.
6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

1. COMPANY NAME AND ADDRESS
(include name, street address, city state, country, and post office code)

OSTEOGENICS BIOMEDICAL INC
4620 71ST STREET
LUBBOCK TX 79424
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)

(b) (4)

2. CONTACT NAME

Dustyn Webb

2.1 E-MAIL ADDRESS

dustyn@cytoplast.com

2.2 TELEPHONE NUMBER (include Area code)

806-7961923

2.3 FACSIMILE (FAX) NUMBER (Include Area code)

806-7960059

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/dc/mdufma>)

Select an application type:

- Premarket notification(510(k)); except for third party
- Biologics License Application (BLA)
- Premarket Approval Application (PMA)
- Modular PMA
- Product Development Protocol (PDP)
- Premarket Report (PMR)

3.1 Select one of the types below

- Original Application

Supplement Types:

- Efficacy (BLA)
- Panel Track (PMA, PMR, PDP)
- Real-Time (PMA, PMR, PDP)
- 180-day (PMA, PMR, PDP)

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 required qualifying documents to FDA
- NO, I am not a small business

4.1 (b) (4) [Redacted]

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

- This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
- The sole purpose of the application is to support conditions of use for a pediatric population
- This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
- The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

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).)

- YES
- NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b) (4) [Redacted]

17-Jul-2007

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission 07/25/2007	User Fee Payment ID Number (b) (4)	FDA Submission Document Number (if known)
----------------------------------	---------------------------------------	---

SECTION A TYPE OF SUBMISSION

PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input type="checkbox"/> Traditional <input type="checkbox"/> Special <input checked="" type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

Have you used or cited Standards in your submission? Yes No (If Yes, please complete Section I, Page 5)

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name Osteogenics Biomedical, Inc.	Establishment Registration Number (if known) 1650372		
Division Name (if applicable)	Phone Number (including area code) (806) 796-1923		
Street Address 4620 71st Street, Bldg 78-79	FAX Number (including area code) (806) 796-0059		
City Lubbock	State / Province TX	ZIP/Postal Code 79424	Country USA
Contact Name Mr. Dustyn Webb			
Contact Title Regulatory/Quality Manager	Contact E-mail Address dustyn@cytoplast.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name (if applicable)	Phone Number (including area code) ()		
Street Address	FAX Number (including area code) ()		
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

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SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address

Other Reason (specify):

SECTION D2 REASON FOR APPLICATION - IDE

<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Repose to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final		

Other Reason (specify):

SECTION D3 REASON FOR SUBMISSION - 510(k)

<input type="checkbox"/> New Device	<input checked="" type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
-------------------------------------	--	---

Other Reason (specify):

1. New manufacturing site - 4620 71st Street, Bldg 78-79, Lubbock, TX 79424 USA
2. Sterilization process change (same sterility level) - Ethylene Oxide (EO) sterilization
3. Label change - new format, additional symbols, manufacturing address change

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SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information	
1	NBY	2	NBY	3	
4		5		6	
7		8		<input type="checkbox"/> 510 (k) summary attached <input checked="" type="checkbox"/> 510 (k) statement	

Information on devices to which substantial equivalence is claimed (if known)

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	P820083 (PMA #)	1 GORE-TEX Expanded PTFE Suture	1 W.L. Gore & Associates, Inc.
2	K003028	2 Cytoplast Suture	2 Osteogenics Biomedical, Inc.
3		3	3
4		4	4
5		5	5
6		6	6

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification
 Suture, Surgical, Nonabsorbable, Expanded, Polytetrafluoroethylene

	Trade or Proprietary or Model Name for This Device	Model Number
1	Cytoplast PTFE Suture	1 Various models and configurations
2		2
3		3
4		4
5		5

FDA document numbers of all prior related submissions (regardless of outcome)

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

Laboratory Testing
 Animal Trials
 Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code NBY	C.F.R. Section (if applicable) 878.5035	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel General & Plastic Surgery		

Indications (from labeling)
 The Cytoplast PTFE Suture is indicated for use in all types of soft tissue approximation and/or ligation, including use in cardiovascular, dental and general surgeries, as well as repair of the dura mater. It is not indicated for use in ophthalmic surgery, microsurgery and peripheral neural tissue.

Note: Submission of this Information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number (if known)

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

<input type="checkbox"/> Original <input checked="" type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number 1650372		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name Osteogenics Biomedical, Inc.			Establishment Registration Number 1650372		
Division Name (if applicable)			Phone Number (including area code) (806) 796-1923		
Street Address 4620 71st Street, Bldg 78-79			FAX Number (including area code) (806) 796-0059		
City Lubbock		State / Province TX	ZIP/Postal Code 79424	Country USA	
Contact Name Mr. Dustyn Webb		Contact Title Regulatory/Quality Manager		Contact E-mail Address dustyn@cytoplast.com	

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number (b) (4)		<input type="checkbox"/> Manufacturer <input checked="" type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name (b) (4)			Establishment Registration Number (b) (4)		
Division Name (if applicable)			Phone Number (including area code) (b) (4)		
Street Address (b) (4)			FAX Number (including area code) ()		
City (b)		State / Province (b)	ZIP/Postal Code (b)	Country (b)	
Contact Name (b) (4)		Contact Title (b)		Contact E-mail Address	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name			Establishment Registration Number		
Division Name (if applicable)			Phone Number (including area code) ()		
Street Address			FAX Number (including area code) ()		
City		State / Province	ZIP/Postal Code	Country	
Contact Name		Contact Title		Contact E-mail Address	

SECTION I

UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	Guidance Document # 1387	CDRH	Class II special controls guidance document: Surgical sutures; guidance for industry and FDA	Supersedes same title dated 12/19/2002	06/03/2003
2	29:2006 29<861> 29<871> 29<881>	USP	Nonabsorbable surgical suture - Sutures - diameter Sutures - needle attachment Sutures - Tensile strength		06/23/2006
3	10993-1:2003 10993-5:1999	ANSI/AAMI/ISO	Biological evaluation of medical devices - Part 1 - Evaluation and testing Part 5 - Tests for in vitro cytotoxicity		10/31/2005
4	11607:2006	ANSI/AAMI/ISO	Packaging for terminally sterilized medical devices		11/03/2006
5	11135-1:2007	ISO	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices		05/01/2007
6	15223-1:2007	ISO	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements		04/15/2007
7	D4895:2004	ASTM	Standard specification for polytetrafluoroethylene (PTFE) resin produced from dispersion		02/01/2004

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

OSTEOGENICS

B I O M E D I C A L

FDA/CDRH/ODE/PMO
2007 JUL 30 A 10:14
RECEIVED

Via Federal Express

July 25, 2007

Center for Devices and Radiological Health
510(k) Document Mail Center (HFZ 401)
9200 Corporate Boulevard
Rockville, MD 20850

510(k) NOTIFICATION

Re: Submission Type: Abbreviated 510(k)
Device Name: Cytoplast® PTFE Suture
Device Common Name: PTFE nonabsorbable monofilament suture
Predicate Device1: GORE-TEX® Expanded PTFE Suture
Predicate's PMA #: P820083
Predicate Device2: Cytoplast® Suture
Predicate's 510(k) #: K003028
Device Type: Suture, Surgical, Nonabsorbable, Expanded,
Polytetrafluoroethylene
Procode: NBY
Classification Regulation: 878.5035
Classification: Class II (Special Controls Guidance Document)
Panel: General & Plastic Surgery
Submitter: Osteogenics Biomedical, Inc.
Manufacturing Location: 4620 71st Street, Bldg 78-79, Lubbock, TX 79424 USA
Sterilization Type : Ethylene Oxide (EO) (SAL = 1 x 10⁻⁶)
Contact: Mr. Dustyn Webb
Title: Regulatory/Quality Manager
Phone: (806) 796-1923

Dear Sir or Madam,

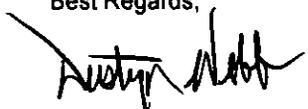
In accordance with the requirements of 21 CFR 807.81, I am pleased to submit herewith duplicate copies of an abbreviated 510(k) submission for the subject device, primarily due to expanded indications (to better match the predicate device's indications, GORE-TEX® Expanded PTFE Suture), and also the issues of a new manufacturing site, sterilization process change and label change.

Please note that all information contained is considered by Osteogenics Biomedical, Inc. to confidential and exempt from public disclosure (21 CFR 807.95).

All data and information contained in this submission is truthful and accurate, and no material fact has been omitted.

I look forward to your favorable consideration of this abbreviated 510(k) submission at your earliest convenience.

Best Regards,



Dustyn Webb
Regulatory/Quality Manager

K22



4620 71st Street, Bldg 78 • Lubbock, TX 79424
phone 888.796.1923 • fax 806.796.0059
osteogenics@cytoplast.com • www.cytoplast.com

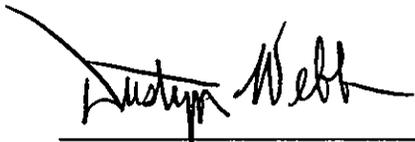


Design and Use of the Device Cytoplast[®] PTFE Suture

- Intended for prescription use
- Not intended for over-the-counter use
- Synthetic composition
- Provided sterile (EO sterilization)
- Intended for single use
- Not reprocessed
- No drug component
- No biologic component
- No software
- Abbreviated 510(k), no clinical information submitted
- Nonabsorbable biocompatible suture, sometimes implanted

510(k) STATEMENT

Osteogenics Biomedical, Inc. will hold and provide a copy of the 510(k) submission of Cytoplast[®] PTFE Suture, with certain exclusions, to any person within 30 days of a written request.



Dustyn Webb
Regulatory/Quality Manager

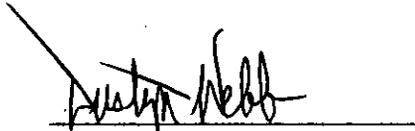
7/25/07
Date

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURACY STATEMENT

(AS REQUIRED BY 21 CFR 807.87 (J))

I certify that, in my capacity as Regulatory/Quality Manager of Osteogenics Biomedical, Inc., I believe, to the best of my knowledge, that all data and information submitted in the Abbreviated 510(k) Premarket Notification are truthful and accurate, and that no material fact has been omitted.



Dustyn Webb
Regulatory/Quality Manager
Osteogenics Biomedical, Inc.

7/26/07

Date

Declaration of Conformity

PRODUCT IDENTIFICATION

Product Name

Cytoplast® PTFE Suture

Model/Number

Various diameters, lengths and
needle configurations

MANUFACTURER

Company Name

Osteogenics Biomedical, Inc.

Address

4620 71st Street, Bldg 78-79
Lubbock, Texas 79424

Representative

Mr. Dustyn Webb
Regulatory/Quality Manager

CONFORMITY ASSESSMENT

Guidance Document

Class II Special Controls Guidance Document: Surgical Sutures;
Guidance for Industry and FDA (June 3, 2003)

Standards Applied

USP 29	ISO 10993-1,5
USP 29 <861>	ISO 11607
USP 29 <871>	ISO 11135-1
USP 29 <881>	ISO 15223-1
	ASTM D4895

Osteogenics Biomedical, Inc. declares that the above mentioned products meet the provisions of the Guidance Document and Standards Applied. All supporting documentation is retained at the premises of the manufacturer.

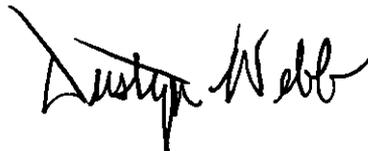
COMPANY REPRESENTATIVE:

Mr. Dustyn Webb

TITLE:

Regulatory/Quality Manager

SIGNATURE:



DATE:

7/25/07

Guidance for Industry and FDA Staff

Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA

Document issued on: June 3, 2003

**This document supersedes “Class II Special Controls Guidance Document:
Surgical Sutures; Guidance for Industry and FDA” dated December 19, 2002.**

For questions regarding this document contact Mr. Stephen P. Rhodes at 240-276-3600 or by email at stephen.rhodes@fda.hhs.gov.



**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health**

**Plastic and Reconstructive Surgery Devices Branch
Division of General, Restorative, and Neurological Devices
Office of Device Evaluation**

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852.

When submitting comments with respect to absorbable polydioxanone surgical suture (21 CFR 878.4840), please refer to the exact title of this guidance document. When submitting comments with respect to sutures **other than** the absorbable polydioxanone surgical suture, please refer to Docket No. 02D-0289. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet at: <http://www.fda.gov/cdrh/ode/guidance/1387.pdf>, or to receive this document by fax, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1387) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

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Guidance for Industry and FDA Staff

Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

1. Introduction

This guidance document was developed as a special control guidance to support the reclassification of the absorbable polydioxanone surgical (PDS) suture into class II. It was also developed as the special control for eight other surgical suture devices previously classified into class II. All nine surgical sutures are listed in **Table 1**. The devices are intended for use in soft tissue approximation, including use in ophthalmic surgery and in pediatric cardiovascular surgery where tissue growth is expected to occur.

On December 19, 2002, this guidance document was issued in conjunction with a Federal Register notice announcing the reclassification of the absorbable PDS suture.

In the same December 19, 2002 issue of the Federal Register, FDA proposed amending the classification regulations for the eight other surgical suture devices previously classified into class II to designate this guidance document as the special control for each suture device. Now, this guidance document is updated and re-issued in conjunction with a Federal Register notice announcing the designation of special controls for these eight surgical suture devices.

This 2003 guidance document supersedes "Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA" dated December 19, 2002.

Following the effective date of this final reclassification rule, any firm submitting a premarket notification (510(k)) for a surgical suture will need to address the issues covered in the special control guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are

Contains Nonbinding Recommendations

cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

2. Background

FDA believes that special controls, when combined with the general controls, will be sufficient to provide reasonable assurance of the safety and effectiveness of these surgical suture devices. Thus, a manufacturer who intends to market a device of this generic type should (1) conform to the general controls of the Federal Food, Drug & Cosmetic Act (the Act), including the 510(k) requirements described in 21 CFR 807 Subpart E, (2) address the specific risks to health associated with surgical suture devices identified in this guidance, and (3) obtain a substantial equivalence determination from FDA prior to marketing the device. (See also 21 CFR 807.85).

This special control guidance document identifies the classification regulations and product codes for the surgical sutures to which it applies (refer to Section 4 – **Scope**). In addition, other sections of this special control guidance document list the risks to health identified by FDA and describe measures that, if followed by manufacturers and combined with the general controls, will generally address the risks associated with these generic suture types and lead to a timely 510(k) review and clearance. This document supplements other agency documents regarding the specific content requirements of a 510(k) submission. You should also refer to 21 CFR 807.87 and other agency documents on this topic, such as the **510(k) Manual - Premarket Notification: 510(k) - Regulatory Requirements for Medical Devices**, <http://www.fda.gov/cdrh/manual/510kprt1.html>.

As described in the guidance entitled, **The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications; Final Guidance**, <http://www.fda.gov/cdrh/ode/parad510.html>, a manufacturer may submit a Traditional 510(k) or has the option of submitting either an Abbreviated 510(k) or a Special 510(k). FDA believes an Abbreviated 510(k) provides the least burdensome means of demonstrating substantial equivalence for a new device, particularly once a special controls guidance document has been issued. Manufacturers considering modifications to their own cleared devices may lessen the regulatory burden by submitting a Special 510(k).

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe need to be addressed before your device can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to comply with the statutory and regulatory criteria in the manner suggested by the guidance and in your attempt to address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the issues, you should follow the procedures outlined in the “**A Suggested Approach to Resolving Least Burdensome Issues**” document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>.

3. The Content and Format of an Abbreviated 510(k) Submission

An Abbreviated 510(k) submission must include the required elements identified in 21 CFR 807.87, including the proposed labeling for the device sufficient to describe the device, its intended use, and the directions for its use. In an Abbreviated 510(k), FDA may consider the contents of a summary report to be appropriate supporting data within the meaning of 21 CFR 807.87(f) or (g); therefore, we recommend that you include a summary report. The report should describe how this special control guidance document was used during the device development and testing and should briefly describe the methods or tests used and a summary of the test data or description of the acceptance criteria applied to address the risks identified in this guidance document, as well as any additional risks specific to your device. This section suggests information to fulfill some of the requirements of 807.87 as well as some other items that we recommend you include in an Abbreviated 510(k).

Coversheet

The coversheet should prominently identify the submission as an Abbreviated 510(k) and cite the title of this Class II Special Controls Guidance Document.

Proposed labeling

Proposed labeling should be sufficient to describe the device, its intended use, and the directions for its use. (Refer to Section 11 for specific information that should be included in the labeling for devices of the types covered by this guidance document.)

Summary report

The summary report should contain:

- Description of the device and its intended use. We recommend that the description include a complete discussion of the performance specifications and, when appropriate, detailed, labeled drawings of the device. (Refer to Section 5 for specific information that we recommend you include in the device description for devices of the types covered by this guidance document.) You should also submit an "indications for use" enclosure.¹
- Description of device design requirements.
- Identification of the Risk Analysis method(s) used to assess the risk profile in general as well as the specific device's design and the results of this analysis. (Refer to Section 6 for the risks to health generally associated with the use of this device that FDA has identified.)

¹ Refer to <http://www.fda.gov/cdrh/ode/indicate.html> for the recommended format.

Contains Nonbinding Recommendations

- Discussion of the device characteristics that address the risks identified in this Class II Special Controls Guidance Document, as well as any additional risks identified in your risk analysis.
- A brief description of the test method(s) you have used or intend to use to address each performance aspect identified in Sections 7-10 of this Class II Special Controls Guidance document. If you follow a suggested test method, you may cite the method rather than describing it. If you modify a suggested test method, you may cite the method but should provide sufficient information to explain the nature of and reason for the modification. For each test, you may either (1) briefly present the data resulting from the test in clear and concise form, such as a table, **or** (2) describe the acceptance criteria that you will apply to your test results.² (See also 21 CFR 820.30, Subpart C - Design Controls for the Quality System Regulation.)
- If any part of the device design or testing relies on a recognized standard, (1) a statement that testing will be conducted and meet specified acceptance criteria before the product is marketed, or (2) a declaration of conformity to the standard.³ Please note that testing must be completed before submitting a declaration of conformity to a recognized standard. (21 USC 514(c)(2)(B)). For more information, see FDA guidance, **Use of Standards in Substantial Equivalence Determinations; Final Guidance for Industry and FDA**, <http://www.fda.gov/cdrh/ode/guidance/1131.html>.

If it is not clear how you have addressed the risks identified by FDA or through your risk analysis, we may request additional information about aspects of the device's performance characteristics. We may also request additional information if we need it to assess the adequacy of your acceptance criteria. (Under 21 CFR 807.87(l), we may request any additional information that is necessary to reach a determination regarding substantial equivalence.)

As an alternative to submitting an Abbreviated 510(k), you can submit a traditional 510(k) that provides all of the information and data required under 21 CFR 807.87 and described in this guidance. A traditional 510(k) should include all of your methods, data, acceptance criteria, and conclusions. Manufacturers considering modifications to their own cleared devices should consider submitting Special 510(k)s.

² If FDA makes a substantial equivalence determination based on acceptance criteria, the subject device should be tested and shown to meet these acceptance criteria before being introduced into interstate commerce. If the finished device does not meet the acceptance criteria, and thus differs from the device described in the cleared 510(k), FDA recommends that submitters apply the same criteria used to assess modifications to legally marketed devices (21 CFR 807.81(a)(3)) to determine whether marketing of the finished device requires clearance of a new 510(k).

³ See Required Elements for a Declaration of Conformity to a Recognized Standard (SCREENING CHECKLIST FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS), <http://www.fda.gov/cdrh/ode/reqrecstand.html>.

Contains Nonbinding Recommendations

The general discussion above applies to any device subject to a special controls guidance document. The following is a specific discussion of how you should apply this special controls guidance document to a 510(k) for a surgical suture.

4. Scope

The scope of this guidance document is limited to the following devices listed in **Table 1**.

Table 1: Designated Surgical Sutures

Suture Name	Regulation	Procode
Absorbable Polydioxanone Surgical (PDS) Suture	21 CFR §878.4840	NEW
Absorbable Poly(glycolide/L-lactide) Surgical Suture	21 CFR §878.4493	GAM
Absorbable Gut Suture	21 CFR §878.4830	GAL
Nonabsorbable Poly(Ethylene Terephthalate) Suture	21 CFR §878.5000	GAT
Nonabsorbable Polypropylene Surgical Suture	21 CFR §878.5010	GAW
Nonabsorbable Polyamide Surgical Suture	21 CFR §878.5020	GAR
Natural Nonabsorbable Silk Surgical Suture	21 CFR §878.5030	GAP
Stainless Steel Surgical Suture	21 CFR §878.4495	GAQ
Nonabsorbable Expanded Polytetrafluoroethylene (ePTFE) Surgical Suture	21 CFR §878.5035	NBY

5. Device Description

We recommend that you identify your suture, by regulation and product code (see Section 4 - Scope), and include the following information:

- the identity and percentages of all materials (including coatings and additives)
- the sizes of sutures using the size system identified in the currently recognized United States Pharmacopoeia (USP)
- the listing as described in 21 CFR 70.5(c) that identifies the color additive, if used. All sutures must meet the requirements of 21 CFR 70.5(c) regarding the use of color additives in sutures. For color additives not already approved for use in your suture material, you must obtain approval of a color additive petition from the Center for Food Safety and Applied Nutrition, in accordance with 21 CFR Part 71, prior to submission of a 510(k).

6. Risks to Health

In the table below, FDA has identified the risks to health generally associated with the use of the surgical suture devices addressed in this document. The measures recommended to mitigate these identified risks are given in this guidance document, as shown in the table below. You should also conduct a risk analysis, prior to submitting your 510(k), to identify any other risks specific to your device. Your 510(k) should describe the risk analysis method. If you elect to use an alternative approach to address a particular risk identified in this guidance document, or have identified risks additional to those in the guidance, you should provide sufficient detail to support the approach you have used to address that risk.

Identified risk	Recommended mitigation measures
Improper selection and use	Sections 10 and 11
Suture breakage	Sections 9 and 10
Adverse tissue reaction	Sections 7 and 10
Infection	Sections 8 and 10

7. Biocompatibility

FDA recommends that you conduct biocompatibility testing as described in the FDA-modified **Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing**, <http://www.fda.gov/cdrh/g951.html>. You should conduct testing appropriate to the body contact and contact duration in your indications for use, typically for sutures, the testing described in Parts 5 (*in vitro* cytotoxicity) and 10 (irritation and sensitization) of ISO-10993.

8. Sterility

We recommend that you provide sterilization information for the finished suture in accordance with the **Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA**, <http://www.fda.gov/cdrh/ode/guidance/361.html>.

9. Physical/Performance Characteristics

We recommend that all surgical sutures conform to the monographs and sections listed below of the currently FDA-recognized edition of the USP. We recommend that you conduct all testing on the sterilized suture in finished form (e.g., needled, in reels) as per the Monograph for Nonabsorbable Sutures or as per the Monograph for Absorbable Sutures. The testing in these monographs include:

- Sutures - Diameter <861>
- Sutures - Needle Attachment <871>

Contains Nonbinding Recommendations

- Tensile Strength <881>.

Resorption Profile

For all absorbable sutures, we recommend that you demonstrate the resorption profile of the final sterilized suture *in vivo* or *in vitro*. The resorption profile should contain a chart, table, or graph that illustrates the residual tensile strength of the suture for a clinically significant period of time. The length of time considered clinically significant depends on the suture's intended use. We recommend that you show that the resorption profile is consistent with the intended use. Examples of intended uses of absorbable surgical sutures are short-term and long-term approximation of tissue.

The numbers of sutures tested should be sufficient to demonstrate that the tensile strength retention of the surgical suture will be consistent. This usually consists of testing at least the largest and smallest sizes of your suture, as well as the sizes in between, skipping no more than two size differences between sizes tested. For example, if you intend to market all suture sizes from 7 to 7-0, we recommend that you test the sizes 7, 4, 1, 2-0, 5-0, and 7-0 for tensile strength retention.

10. Clinical Studies

In accordance with the Least Burdensome provisions of the FDA Modernization Act of 1997, the agency will rely upon well-designed bench and/or animal testing rather than requiring clinical studies for new devices unless there is a specific justification for asking for clinical information to support a determination of substantial equivalence. While, in general, clinical studies will not be needed for most surgical suture devices, FDA may recommend that you collect clinical data for a surgical suture device with:

- a formulation dissimilar from formulations previously cleared under a 510(k);
- a new technology, i.e., technology different from that used in legally marketed surgical suture devices; or
- indications for use dissimilar from indications for use of sutures of the same type.

FDA will always consider alternatives to clinical testing when the proposed alternatives are supported by an adequate scientific rationale. The Plastic and Reconstructive Surgery Devices Branch is available to discuss any clinical testing with you before you initiate studies.

After FDA determines that the device is substantially equivalent, clinical studies conducted in accordance with the indications reviewed in the 510(k), including clinical design validation studies conducted in accordance with the quality systems regulation, are exempt from the investigational device exemptions (IDE) requirements. However, such studies must be performed in conformance with the regulations governing institutional review boards (21 CFR 56) and informed consent (21 CFR 50).

Contains Nonbinding Recommendations

If a clinical study is needed to demonstrate substantial equivalence, i.e., conducted prior to obtaining 510(k) clearance of the device, the study must be conducted under the IDE regulation (21 CFR 812). FDA has determined that sutures addressed by this guidance document are significant risk devices as defined in 21 CFR 812.3(m)(4).⁴ In addition to the requirement of having an FDA-approved IDE, sponsors of such trials must comply with Parts 50 and 56.

11. Labeling

The 510(k) should include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). The following suggestions are aimed at assisting you in preparing labeling that satisfies the requirements of 21 CFR 807.87(e).⁵

Reference to USP

If your suture meets all requirements established by the USP for Non-absorbable Surgical Sutures, Absorbable Surgical Sutures, or Synthetic Absorbable Surgical Sutures, we recommend that you state this in the labeling.

FDA permits reference to USP only when all USP specifications are met. If one or more USP specifications are not met, you should not reference USP in the trade or generic name. If your suture does not meet all USP requirements, the labeling should clearly state that suture is non-USP and describe the respects in which it is non-USP.

Description

The description should:

- state whether the suture is absorbable or non-absorbable;
- give the material composition or biological (species and tissue) sources; and
- list any packing fluids, dyes, or coatings.

Indications

The indications should list the kinds of surgery, sites in the body, and, in some instances, the patient populations where the suture is intended to be used.

⁴ Refer to Blue Book Memorandum entitled "SIGNIFICANT RISK AND NONSIGNIFICANT RISK MEDICAL DEVICE STUDIES" at <http://www.fda.gov/cdrh/d861.html>.

⁵ Although final labeling is not required for 510(k) clearance, final labeling must also comply with the requirements of 21 CFR 801 before a medical device is introduced into interstate commerce. In addition, final labeling for prescription medical devices must comply with 21 CFR 801.109. Labeling recommendations in this guidance are consistent with the requirements of part 801.

Contains Nonbinding Recommendations

Performance

For absorbable sutures, the labeling should describe:

- how the suture is absorbed and the rate of absorption;
- how tensile strength changes over time; and
- when absorption is usually complete.

For non-absorbable sutures, the labeling should describe whether any significant loss of tensile strength occurs over time.

In addition, your labeling should state “For Single Use Only.”

Contraindications

You should list the contraindications appropriate to your suture. Contraindications should include any surgery types, body sites, or patient populations where evidence demonstrates that the suture should not be used.

Warnings

You should list the warnings appropriate to your suture. A complete warning is a statement that not only describes the serious adverse reactions or potential safety hazards associated with the device but also includes the possible consequence. As an example, consider the warning, “Avoid prolonged contact with urine or bile.” A better written or complete warning would include the consequence and, thus, state “Prolonged contact with urine or bile may result in calculus formation.”

Precautions

You should list the precautions appropriate to your suture. A precaution is a statement that informs users of the measures they should take to avoid adverse events or potential safety hazards while using the device. For example, “Avoid crushing or crimping the suture when handling it with forceps or needle holders. Crushing or crimping may adversely affect the tensile strength or absorption rate of the suture.” As with warnings, precautions should include the consequence.

Adverse Reactions

You should identify adverse reactions associated with the use of the suture. You should list separately adverse reactions observed with all sutures versus those adverse reactions observed only with your suture type.

How Supplied

You should state whether your suture is supplied sterile, in cut lengths or ligating reels, and affixed to needles or non-needed. You should also list the sizes and per unit packaging (e.g., one-, two-, and three- dozen box) available.

510(K) EXECUTIVE SUMMARY

A. Submitters Information

Type: Abbreviated 510(k) Submission
Name: Osteogenics Biomedical, Inc.
Address: 4620 71th Street, Bldg 78-79
Lubbock, TX. 79424
FDA Establishment #: 1650372
Telephone: 806-796-1923
Fax: 806-796-0059
Contact Person: Dustyn Webb
Date of Submission: July 25, 2007

B. Device Name

Cytoplast[®] PTFE Suture

C. Predicate Devices

GORE-TEX[®] Expanded PTFE Suture (W.L. Gore & Associates, Inc.)
PMA #: P820083

Cytoplast[®] Suture (Osteogenics Biomedical, Inc.)
510(k) #: K003028

D. Device Description

Cytoplast[®] PTFE Suture is a nonabsorbable, sterile surgical monofilament suture composed of polytetrafluoroethylene that is expanded providing a microporous structure. The Cytoplast[®] PTFE Suture meets or exceeds all requirements in the USP 29 monograph for nonabsorbable surgical sutures. The material is undyed and contains no additives. Cytoplast[®] PTFE Suture is provided sterile with attached standard surgical needles in a variety of sizes and configurations.

E. Intended Use

Cytoplast[®] PTFE Suture is indicated for use in approximation and/or ligation of soft tissue, including use in cardiovascular, dental and general surgery, as well as repair of the dura mater. It is not indicated for use in ophthalmic surgery, microsurgery and peripheral neural tissue.

F. Technological Characteristics

The Cytoplast® PTFE Suture and the predicate device, GORE-TEX® Expanded PTFE Suture, are of the same composition (100% polytetrafluoroethylene) and are indicated for the same use (see indications for use). The technological characteristics of the materials are the same as the predicate device.

G. Performance Data

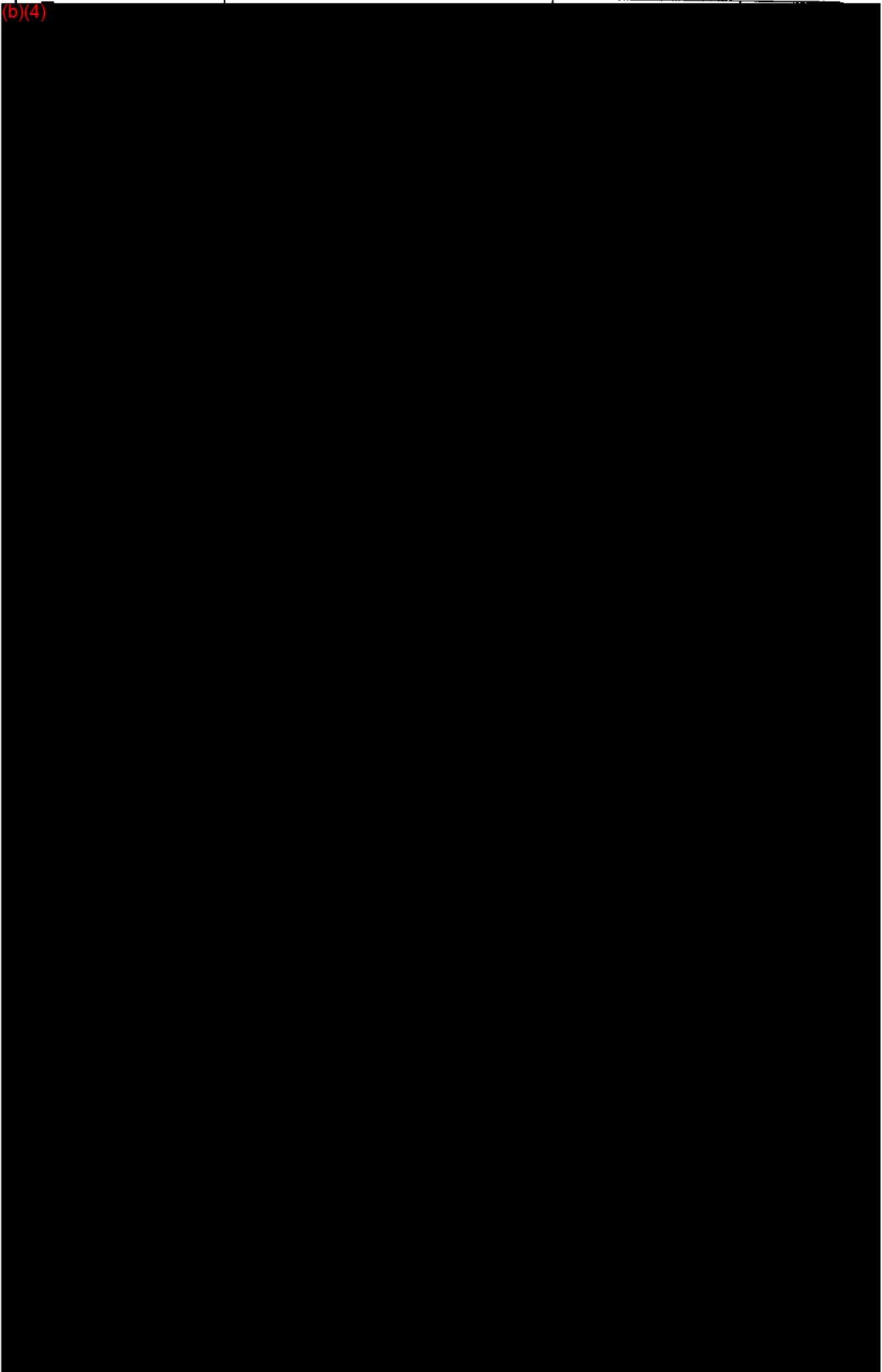
Polytetrafluoroethylene has been shown to be non-toxic and biologically inert. PTFE sutures are biocompatible and effective in the approximation and/or ligation of soft tissue, including implantation. Cytoplast® PTFE Suture (marketed as Cytoplast® Suture – 510(k) # K003028) has been marketed successfully (b) (4) since 2002, without any recalls or adverse events.

COMPARATIVE INFORMATION

	Subject Device	Predicate Device1	Predicate Device2
Trade Name	Cytoplast® PTFE Suture	GORE-TEX® Expanded PTFE Suture PMA #: P820083	Cytoplast® Suture 510(k) #: K003028
Common Name	PTFE nonabsorbable suture	PTFE nonabsorbable suture	PTFE nonabsorbable suture
Classification Name	Suture, Surgical, Nonabsorbable, Expanded, Polytetrafluoroethylene	Suture, Surgical, Nonabsorbable, Expanded, Polytetrafluoroethylene	Suture, Surgical, Nonabsorbable, Expanded, Polytetrafluoroethylene
Indications for Use	Cytoplast® PTFE Suture is indicated for all types of soft tissue approximation and/or ligation, including cardiovascular, dental and general surgery, as well as repair of the dura mater. The device is not indicated for use in ophthalmic surgery, microsurgery and peripheral neural tissue.	The GORE-TEX® Expanded PTFE Suture is indicated for use in all types of soft tissue approximation, including use in cardiovascular surgery and dura mater repair, but not in ophthalmic surgery, microsurgery and peripheral neural tissue.	A removable, nonabsorbable suture for approximation and ligation of soft tissue in the oral cavity, including fixation of barrier membranes.
Labeling	Sterile, Single Use	Sterile, Single Use	Sterile, Single Use
Chemical Composition	100% PTFE	100% PTFE	100% PTFE
Structure of Material	Expanded	Expanded	Expanded
Porosity	Meets USP Standards	≤ 50% air/volume	Meets USP Standards
Performance	Ethylene Oxide	Does not claim USP Standards	Initial 510(k) – Steam Changed to Ethylene Oxide
Method of Sterilization	Ethylene Oxide	Ethylene Oxide	Initial 510(k) – Steam Changed to Ethylene Oxide
Biocompatibility	Established	Established	Established
Product Availability	Various Sizes	Various Sizes	Various Sizes

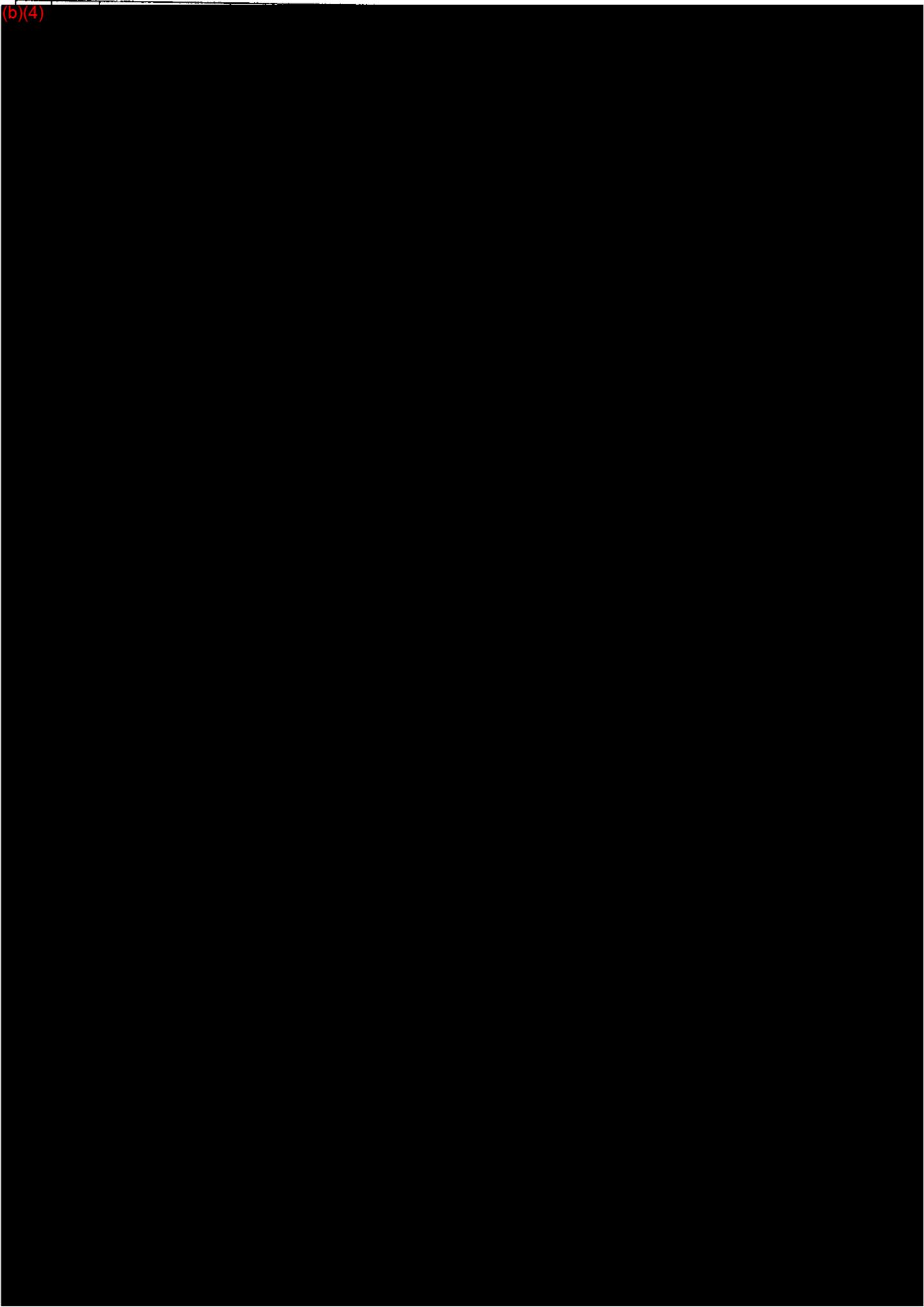
Risk Management Report

(b)(4)



Cytoplast PTFE Monofilament Sutures

(b)(4)





DEVICE DESCRIPTION/ACTIONS

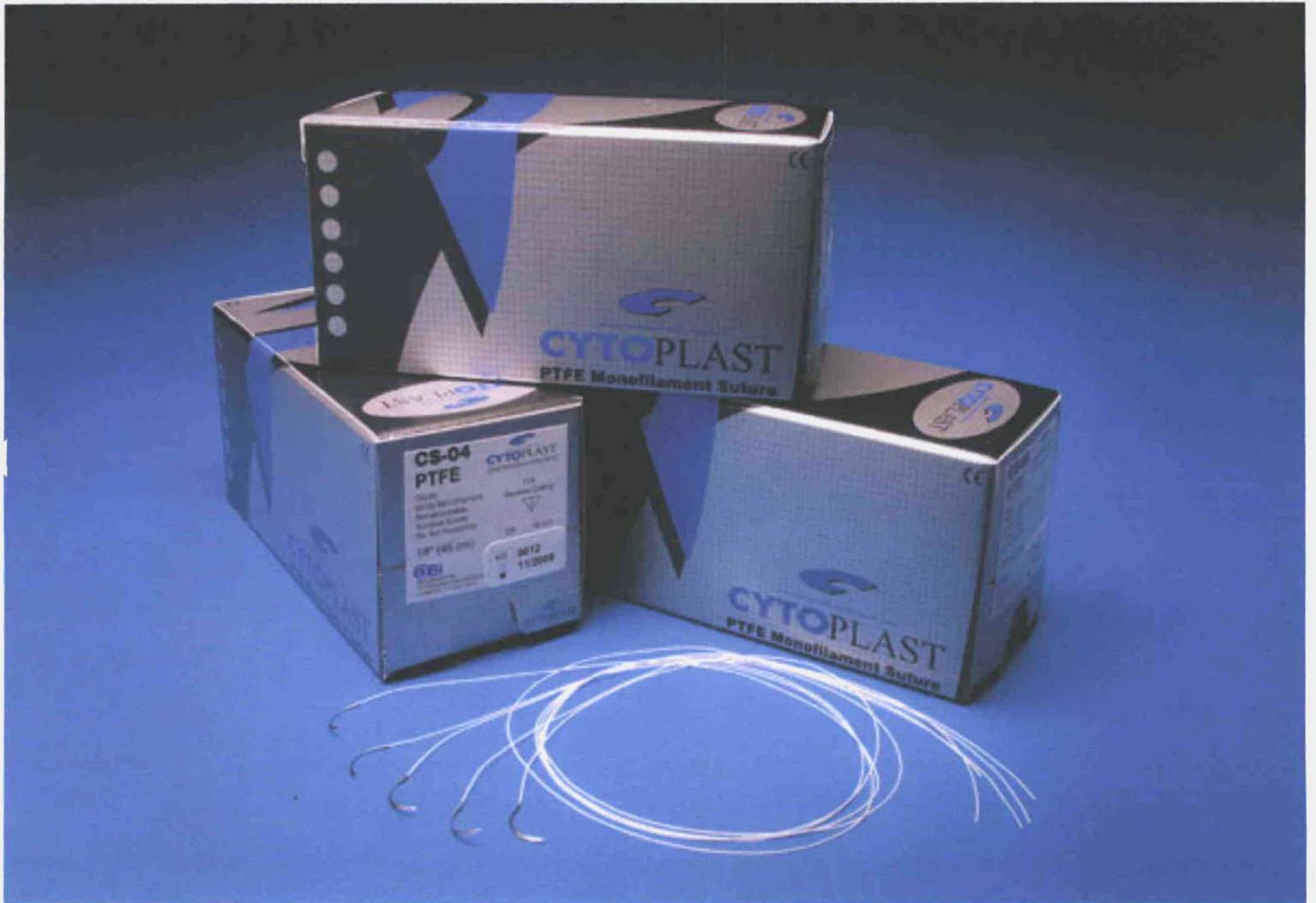
Description:

Cytoplast[®] PTFE Suture is a nonabsorbable, monofilament suture manufactured from 100% high-density polytetrafluoroethylene (PTFE) polymer, extruded in such a fashion as to produce a structure with a minimal pore size and volume while maintaining integrity and tensile strength. The suture is undyed and contains no additives. Cytoplast[®] PTFE Suture meets USP requirements.

Actions:

(b)(4) Trade Secret Process-Product Specs





GENERAL INFORMATION

A. Device Proprietary Name: Cytoplast® PTFE Suture

Models: Various models based on suture diameter size, length and attached needle type

CS-####XXXX

CS	-	##	##	XXXX
		diameter	length	needle
		size		type

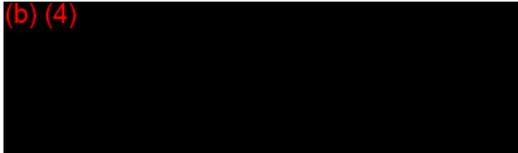
Classification Name: Suture, Surgical, Nonabsorbable, Expanded, Polytetrafluoroethylene

B. Predicate Device: GORE-TEX® Expanded PTFE Suture
PMA #: P820083

Cytoplast® Suture
510(k) #: K003028

C. Establishment Registration Number: 1650372

D. Address of Manufacturing Facility:
Osteogenics Biomedical, Inc.
4620 71th Street, Bldg 78-79
Lubbock, Texas 79424



E. Section 513 Classification: Class II; 21 CFR 878.5035

Procode: NBY

Panel: General & Plastic Surgery

F. Reasons for the Premarket Notification:

Major - Indications change

Minor - Manufacturing site change, sterilization method change, label change

G. Performance Standards:

1. Class II special controls guidance document: Surgical sutures; guidance for industry and FDA
2. USP 29 – Nonabsorbable surgical suture
3. USP 29 <861> Sutures – Diameter
4. USP 29 <871> Sutures – Needle attachment
5. USP 29 <881> Sutures – Tensile strength
6. ISO 10993 – Biological Evaluation of medical devices
7. ISO 11607 – Packaging for terminally sterilized medical devices
8. ISO 11135 – Medical devices-Validation and routine control of ethylene oxide sterilization
9. ISO 15223 – Medical devices-Symbols to be used with medical device labels, labeling and information to be supplied
10. ASTM D4895 – Standard specification for polytetrafluoroethylene (PTFE) resin produced from dispersion

510(k) Number If Known: _____

Device Name: Cytoplast® PTFE Suture

Indications for Use:

Cytoplast® PTFE Suture is indicated for use in all types of soft tissue approximation and/or ligation, including use in cardiovascular, dental and general surgeries, as well as repair of the dura mater. It is not indicated for use in ophthalmic surgery, microsurgery and peripheral neural tissue.

(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 CFR 801.109)

Or

Over-the-Counter Use _____

CONFIDENTIAL INFORMATION
Osteogenics Biomedical, Inc.
Cytoplast® PTFE Suture
Abbreviated 510(k) Submission



Cytoplast® PTFE Suture
INSTRUCTIONS FOR USE

Description:

Cytoplast® PTFE Suture is a nonabsorbable, monofilament suture manufactured from 100% high-density polytetrafluoroethylene (PTFE) polymer, extruded in such a fashion as to produce a structure with a minimal pore size and volume while maintaining integrity and tensile strength. The suture is undyed and contains no additives. Cytoplast® PTFE Suture meets USP requirements.

Actions:

PTFE has been shown in clinical trials to elicit minimal tissue reaction. The Cytoplast® PTFE Suture is not absorbed or subject to weakening by tissue enzymes, and does not degrade in the presence of infection.

The minimally porous structure of the suture material, while potentially allowing some ingrowth of cells such as fibroblasts and leukocytes into the outermost layers of the device, does not allow bacteria to invade the suture itself, decreasing inflammation around suture lines.

Indications:

The Cytoplast® PTFE Suture is indicated for use in all types of soft tissue approximation and/or ligation, including cardiovascular, dental and general surgeries, as well as repair of the dura mater. The device is not indicated for use in ophthalmic surgery, microsurgery and peripheral neural tissue.

Contraindications:

There are no known contraindications.

Warnings:

The safety and effectiveness of this suture in ophthalmic, microsurgical, and peripheral neural applications has not been established.

Tissue invasion of Cytoplast® PTFE Suture can result in attachment of the suture to the tissue it penetrates in long-term use. Such attachment may make removal of the suture difficult.

The device is for single use only. Do not resterilize.

Precautions:

Misuse of this suture, like any other suture, can result in severe injury or death to the patient. As with any suture, care should be taken to avoid damage when handling. Avoid crushing or crimping the suture with surgical instruments or exposing the suture to sharp edges. In order to minimize needle damage, do not grasp or drive the needle from near the channel where the suture is attached.

Knot security requires standard surgical techniques of flat and square ties with additional throws as indicated by surgical circumstances and the experience of the surgeon. When tying knots with the Cytoplast® PTFE Suture, tension should be applied by pulling each strand of the suture in opposite directions with equal force. Caution: this tension should not be applied by pulling on the needle itself, but is applied by grasping the suture with the fingers or surgical instruments. As the knot is tensioned, the air in the suture is forced out. Care should be taken to avoid using a jerking motion, which could break the suture or cause separation of the suture from the needle. Uneven tensioning of a well-formed square knot may result in an insecure knot. When the Cytoplast® PTFE Suture is properly tensioned and formed, standard surgical knotting techniques will produce a secure knot.

Sterility:

Cytoplast® PTFE Suture is supplied STERILE unless the integrity of the package has been compromised. The device is for single use only. Do not resterilize.

Adverse Reactions:

None reported.

Dosages and Administration:

Use as required per surgical procedure.

How Supplied:

Cytoplast® PTFE Suture is available as sterile strands in a variety of sizes and lengths with permanently attached needles.

Caution:

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician or dentist.

LABELING SYMBOLS

Symbols may be used on package labeling for easy identification.

	Use By
	Do Not Reuse
	Attention, see instructions for use
	Method of Sterilization Using Ethylene Oxide
	Lot Number
	Catalog Number
	Manufacturer
	Authorized Representative in the European Community

Osteogenics Biomedical, Inc.
4620 71st Street, Bldg 78-79
Lubbock, TX 79424 USA
Tel: 806-796-1923
Toll-free: 888-796-1923
www.cytoplast.com

Emergo Europe
Molenstraat 15
2513 BH, The Hague
The Netherlands

Revised 07/07


CYTOPLAST™
PTFE
 WHITE MONOFILAMENT
 NONABSORBABLE SUTURE
USP 3-0
 Metric 2

 Osteogenics Biomedical, Inc.
 4620 71st Street, Bldg 78-79
 Lubbock, TX 79424 USA
 (888) 796-1923
 www.cytoplast.com

REF CS0518
 Contents: (12) sutures
 18"/45 cm
 CAUTION: Federal (USA) law restricts
 this device to sale by or on the order
 of a physician or dentist.

C22
 Reverse Cutting
 3/8 Circle 16.3 mm

CE 0120

STERILE EO


LOT RC0536
 2011-06

Box Label


CYTOPLAST™
 SIMPLE | PREDICTABLE | PRACTICAL
PTFE
 WHITE MONOFILAMENT
 NONABSORBABLE SUTURE
USP 3-0
 Metric 2
 18"/45 cm

 C22
 Reverse Cutting
 3/8 Circle 16.3 mm

REF CS0518
LOT RC0536
 2011-06

STERILE EO 
CE 0120

CAUTION: Federal (USA) law restricts this device to
 sale by or on the order of a physician or dentist.

 **OSTEOGENICS**
 BIOMEDICAL
 4620 71st Street, Bldg 78-79
 Lubbock, Texas 79424 USA
 888.796.1923
 www.cytoplast.com

Individual Pouch Label

COMPARATIVE INFORMATION

Statement of Equivalence:

For the purposes of Section 510(k) of the Federal Food, Drug and Cosmetic Act, Osteogenics Biomedical, Inc. considers the Cytoplast[®] PTFE Suture to be substantially equivalent to the GORE-TEX[®] Expanded PTFE Suture (W.L. Gore & Associates, Inc.).

Both medical devices are comprised of known, biocompatible materials. Substantial equivalence is readily evidenced by the fact that the composition of the materials, and their intended use are the same.

COMPARATIVE INFORMATION

	Subject Device	Predicate Device1	Predicate Device2
Trade Name	Cytoplast® PTFE Suture	GORE-TEX® Expanded PTFE Suture PMA #: P820083	Cytoplast® Suture 510(k) #: K003028
Common Name	PTFE nonabsorbable suture	PTFE nonabsorbable suture	PTFE nonabsorbable suture
Classification Name	Suture, Surgical, Nonabsorbable, Expanded, Polytetrafluoroethylene	Suture, Surgical, Nonabsorbable, Expanded, Polytetrafluoroethylene	Suture, Surgical, Nonabsorbable, Expanded, Polytetrafluoroethylene
Indications for Use	Cytoplast® PTFE Suture is indicated for all types of soft tissue approximation and/or ligation, including cardiovascular, dental and general surgery, as well as repair of the dura mater. The device is not indicated for use in ophthalmic surgery, microsurgery and peripheral neural tissue.	The GORE-TEX® Expanded PTFE Suture is indicated for use in all types of soft tissue approximation, including use in cardiovascular surgery and dura mater repair, but not in ophthalmic surgery, microsurgery and peripheral neural tissue.	A removable, nonabsorbable suture for approximation and ligation of soft tissue in the oral cavity, including fixation of barrier membranes.
Labeling	Sterile, Single Use	Sterile, Single Use	Sterile, Single Use
Chemical Composition	100% PTFE	100% PTFE	100% PTFE
Structure of Material	Expanded	Expanded	Expanded
Porosity	(b) (4)	≤ 50% air/volume	(b) (4)
Performance	Meets USP Standards	Does not claim USP Standards	Meets USP Standards
Method of Sterilization	Ethylene Oxide	Ethylene Oxide	Initial 510(k) – Steam Changed to Ethylene Oxide
Biocompatibility	Established	Established	Established
Product Availability	Various Sizes	Various Sizes	Various Sizes

STERILIZATION / SHELF LIFE INFORMATION

The Cytoplast® PTFE Suture will be sterilized by ethylene oxide. The sterilization process has been validated in accordance with AMSI/AAMI/ISO 11135:2007 guidelines to provide a minimum Sterility Assurance Level (SAL) of 1×10^{-6} .

The Cytoplast® PTFE Suture has been validated for a four (4) year shelf life.

BIOCOMPATIBILITY

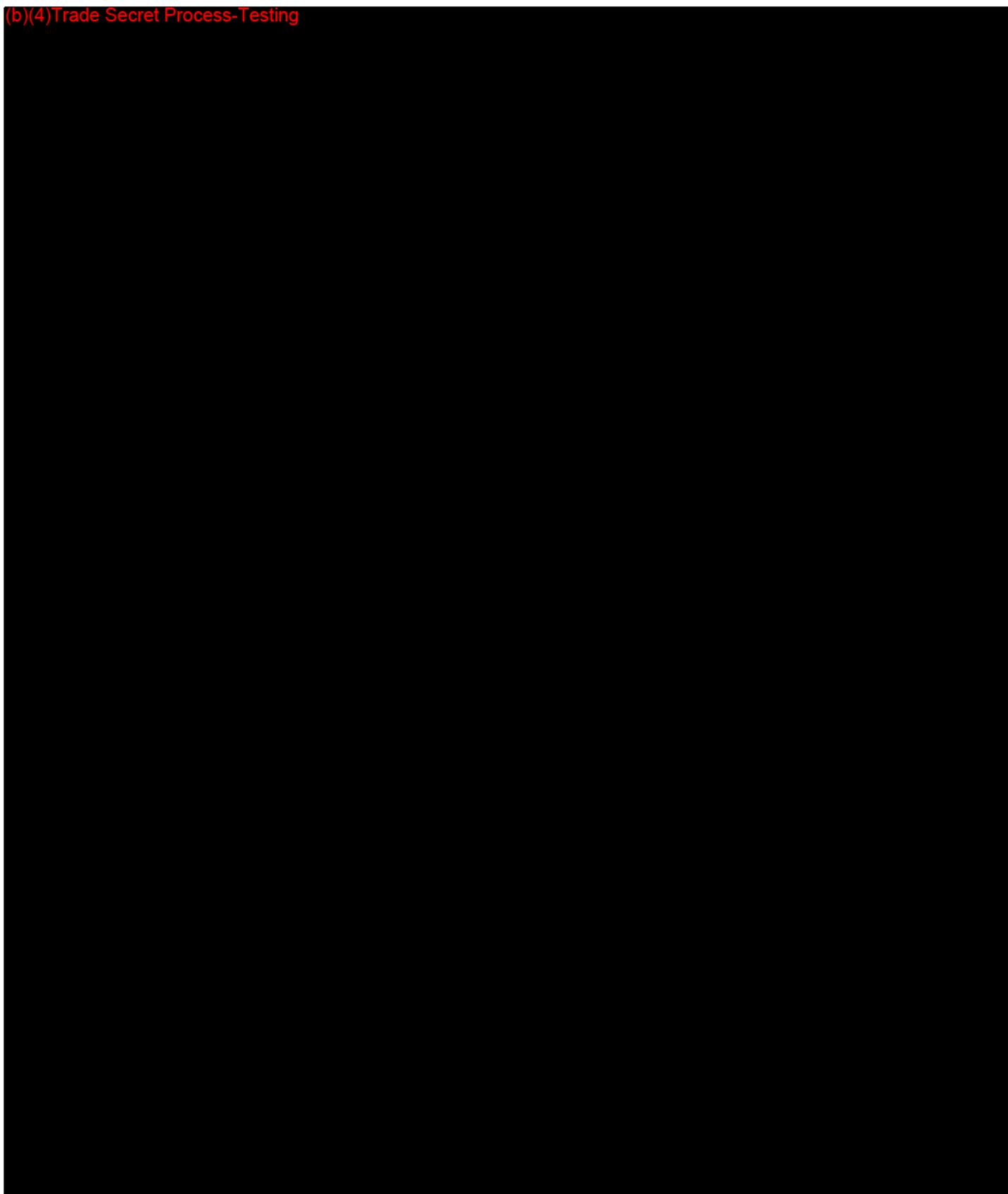
Statement of Equivalence:

For the purposes of Section 510(k) of the Federal Food, Drug, and Cosmetic Act, Osteogenics Biomedical, Inc. considers the Cytoplast® PTFE Suture to be substantially equivalent to the GORE-TEX® Expanded PTFE Suture (W.L. Gore & Associates, Inc.).

Both devices are comprised of known, biocompatible materials. Substantial equivalence is readily evidenced by the fact that the composition of the materials, and their intended use is the same.

BIOCOMPATIBILITY

(b)(4)Trade Secret Process-Testing



(b)(4)Trade Secret Process-Testing





COVER SHEET MEMORANDUM

From: Reviewer Name Lisa M. Lim Ph.D.
Subject: 510(k) Number K072076/S
To: The Record

Please list CTS decision code SE
 Refused to accept (Note: this is considered the first review cycle, See Screening Checklist, <http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/ScreeningChecklist>)
 Hold (Additional Information or Telephone Hold).
 Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	✓	
510(k) Summary <u>510(k) Statement</u>	Attach Summary	✓	
Truthful and Accurate Statement.	Must be present for a Final Decision	✓	
Is the device Class III?			✓
If yes, does firm include Class III Summary?	Must be present for a Final Decision		
Does firm reference standards? (If yes, please attach form from http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/ABB_REVIATED_STANDARDS_DATA_FORM.DOC)		✓	
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?		✓	✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Is clinical data necessary to support the review of this 510(k)?			✓
Does this device include an Animal Tissue Source?			✓
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	Contact OSB.		✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.		✓

Regulation Number 21 CFR 878.5035 Class* II Product Code NBY
(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____
Review: Daniel Krause PRS B October 26, 2007
(Branch Chief) (Branch Code) (Date)
Final Review: _____ (Date)
(Division Director)

Standards Data Form for Abbreviated 510(k)s

510(k) Number: K072076

Standard Organization No:

or

Standard Identification No:

or

CDRH Internal Reference No:

Class II Special Controls
Guidance Document: Surgical
Sutures (June 3, 2003)

Declaration of Conformity Elements:

Any Adaptations Applied	yes	no	X
Any Requirements Not Applicable	yes	no	X
Any Deviations Applied	yes	no	X
Any Differences in Device Tested and Finished Product	yes	no	X
*Is There a Third Party or Test Lab Involved	yes	no	X

Was there another standard used in the review of this submission? yes X no

If another standard was used, please fill out an additional form.

* This is not the third party that reviews 510ks



Standards Data Form for Abbreviated 510(k)s

510(k) Number: K072076

Standard Organization No: ISO 10993-1, -5

or

Standard Identification No:

or

CDRH Internal Reference No:

Declaration of Conformity Elements:

Any Adaptations Applied	yes	no	X
Any Requirements Not Applicable	yes	no	X
Any Deviations Applied	yes	no	X
Any Differences in Device Tested and Finished Product	yes	no	X
*Is There a Third Party or Test Lab Involved	yes	X	no

Was there another standard used in the review of this submission? yes X no

If another standard was used, please fill out an additional form.

* This is not the third party that reviews 510ks

Standards Data Form for Abbreviated 510(k)s

510(k) Number: K072076

Standard Organization No: ISO 11607

or

Standard Identification No:

or

CDRH Internal Reference No:

Declaration of Conformity Elements:

Any Adaptations Applied	yes	no	X
Any Requirements Not Applicable	yes	no	X
Any Deviations Applied	yes	no	X
Any Differences in Device Tested and Finished Product	yes	no	X
*Is There a Third Party or Test Lab Involved	yes	no	X

Was there another standard used in the review of this submission? yes X no

If another standard was used, please fill out an additional form.

* This is not the third party that reviews 510ks

Standards Data Form for Abbreviated 510(k)s

510(k) Number: K072076

Standard Organization No: ISO 11135-1

or

Standard Identification No:

or

CDRH Internal Reference No:

Declaration of Conformity Elements:

Any Adaptations Applied	yes	no	X
Any Requirements Not Applicable	yes	no	X
Any Deviations Applied	yes	no	X
Any Differences in Device Tested and Finished Product	yes	no	X
*Is There a Third Party or Test Lab Involved	yes	X	no

Was there another standard used in the review of this submission? yes X no

If another standard was used, please fill out an additional form.

* This is not the third party that reviews 510ks

Standards Data Form for Abbreviated 510(k)s

510(k) Number: K072076

Standard Organization No: ISO 15223-1

or

Standard Identification No:

or

CDRH Internal Reference No:

Declaration of Conformity Elements:

Any Adaptations Applied	yes	no	X
Any Requirements Not Applicable	yes	no	X
Any Deviations Applied	yes	no	X
Any Differences in Device Tested and Finished Product	yes	no	X
*Is There a Third Party or Test Lab Involved	yes	no	X

Was there another standard used in the review of this submission? yes X no

If another standard was used, please fill out an additional form.

* This is not the third party that reviews 510ks



Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Abbreviated

K072076/S01

Date: October 26, 2007
To: The Record
From: Lisa M. Lim, Ph.D.

Office: ODE
Division: DGRND

510(k) Holder: Osteogenics Biomedical, Inc.
Device Name: Cytoplast PTFE Suture
Contact: Dustyn Webb, Regulatory/Quality Manager
Phone: (806) 796-1923
Fax: (806) 796-0059
Email: dustyn@cytoplast.com

1. **Recommendation:** SE

Regulation Number: 21 CFR 878.5035
Regulation Name: Suture, surgical, nonabsorbable, expanded, polytetrafluoroethylene
Regulatory Class: Class II
Product Code: NBY

2. **Purpose and Submission Summary**

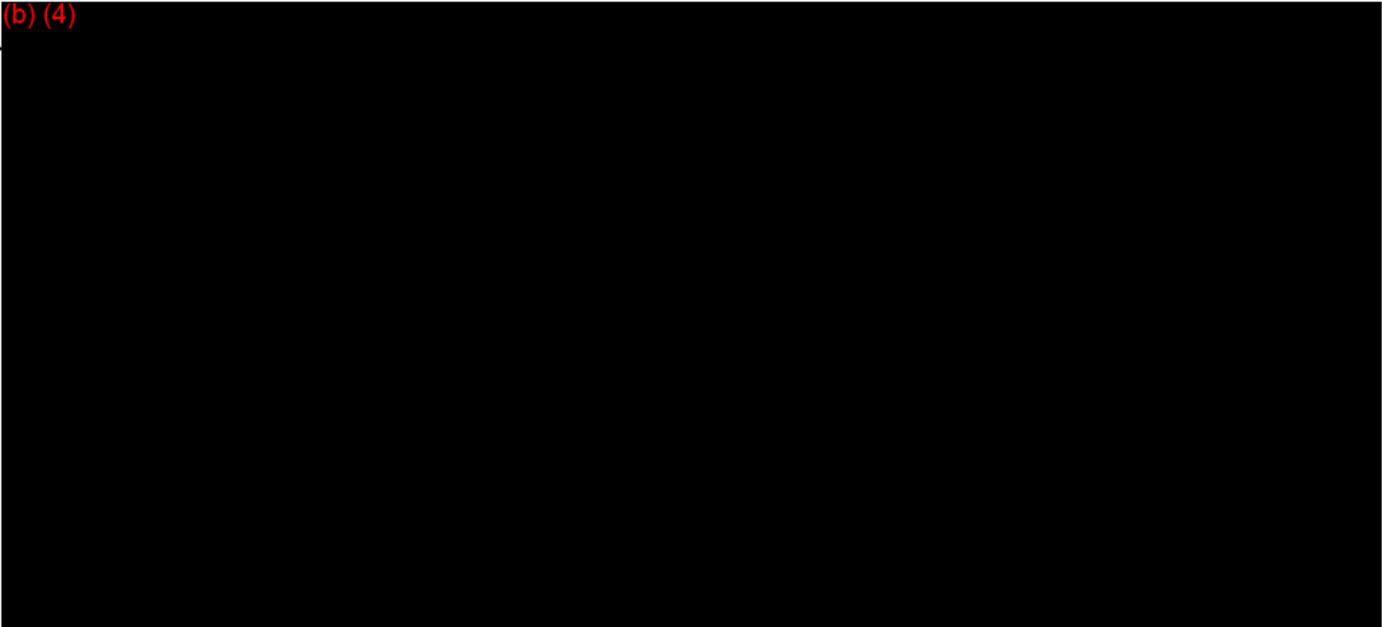
(b) (4)

3. **Administrative Requirements**

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Statement	X		
Standards Form	X		

(b) (4)

(b) (4)



4. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?	X		
Does the device design use software?		X	
Is the device sterile?	X		
Is the device reusable (not reprocessed single use)?		X	
Are "cleaning" instructions included for the end user?		X	

(b) (4)



5. Indications for Use

Subject Device: Cytoplast PTFE Suture is indicated for all types of soft tissue approximation and/or ligation, including cardiovascular, dental and general surgery, as well as repair of the dura mater. The device is not indicated for use in ophthalmic surgery, microsurgery and peripheral neural tissue.

Predicate Devices: The GORE-TEX Expanded PTFE Suture (P820083) is indicated for use in all types of soft tissue approximation, including cardiovascular and dura mater repair, but not in ophthalmic surgery, microsurgery and peripheral neural tissue.



Cytoplast Suture (K003028, Procode: NBY) – A removable, nonabsorbable

suture for approximation and ligation of soft tissue in the oral cavity, including fixation of barrier membranes.

(b) (4)

6. Predicate Device Comparison

(b) (4)

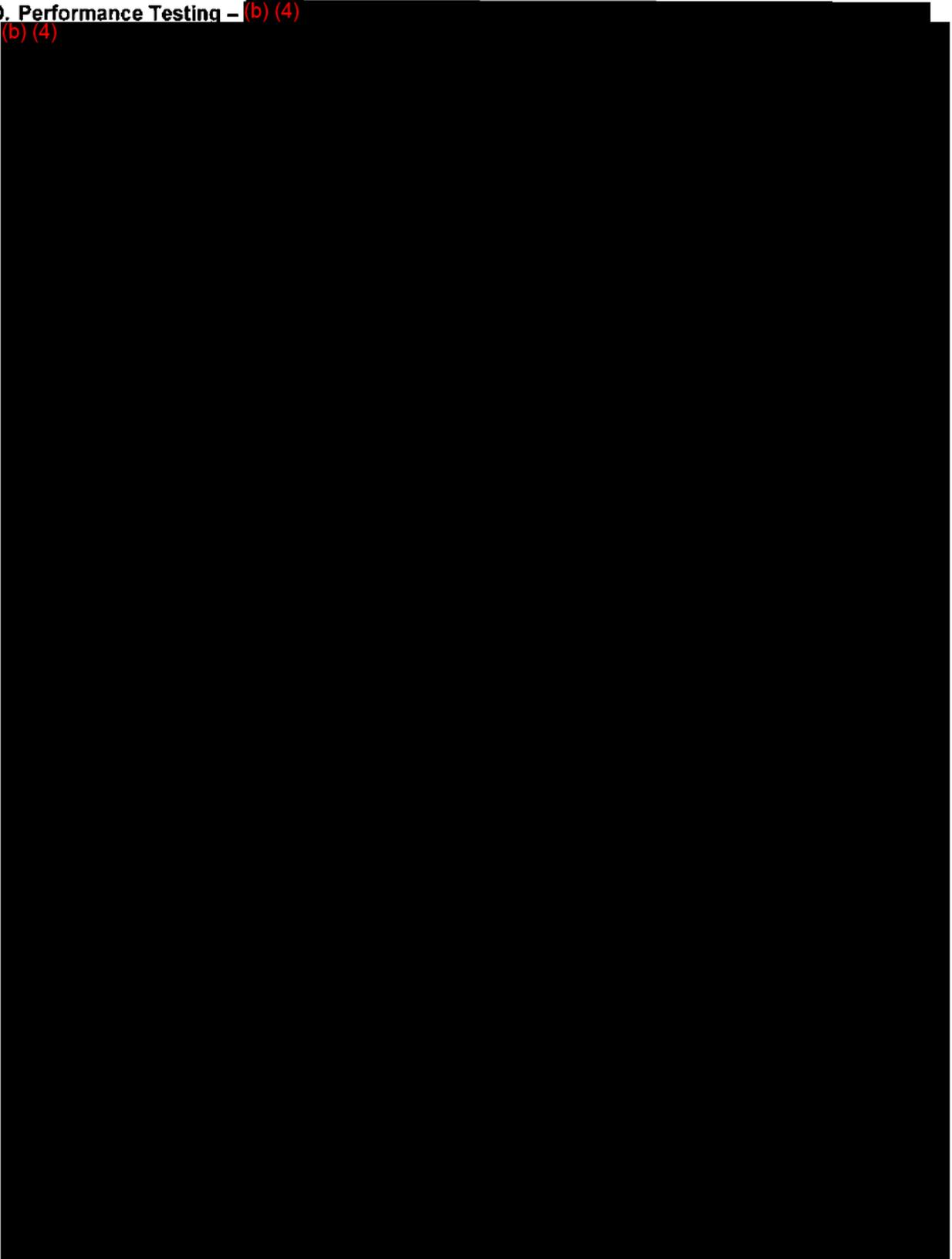
7. Biocompatibility: (b) (4)

(b)
(4)Trad
e

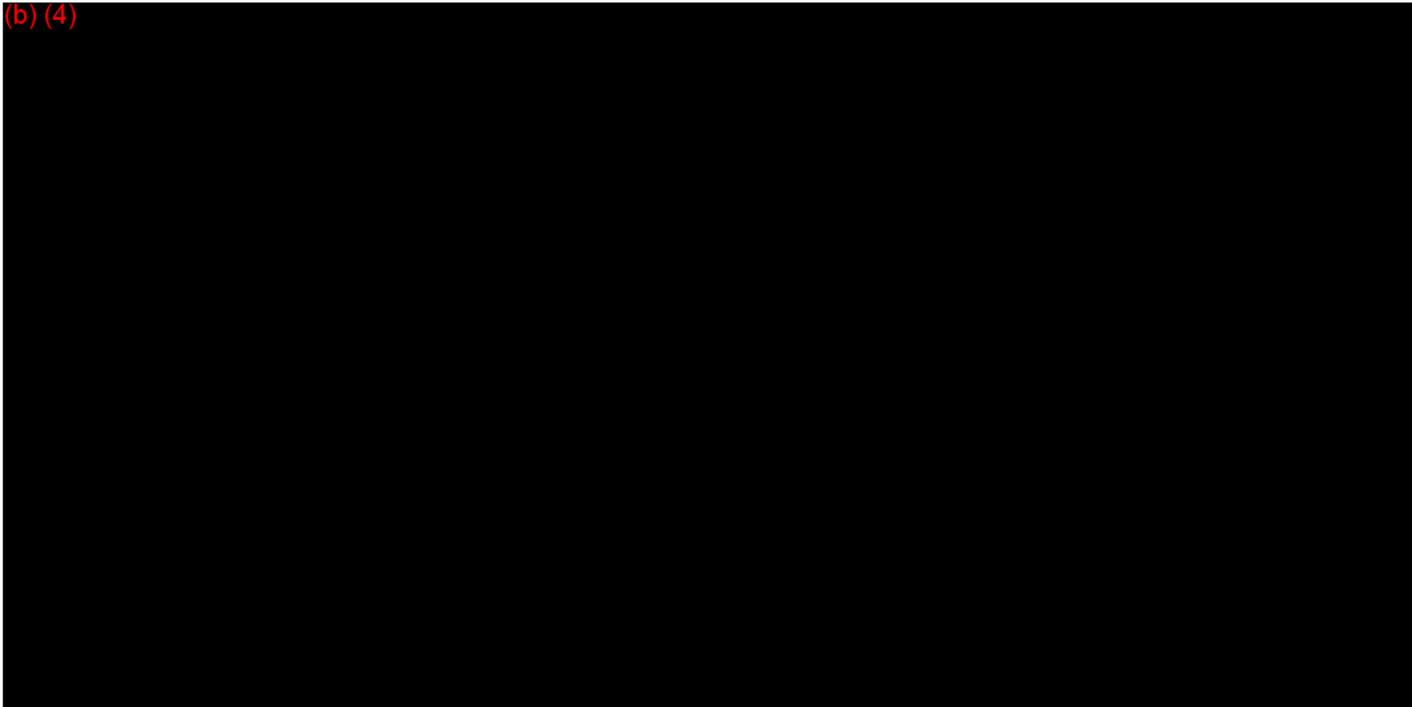
8. Software: N/A

9. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety: N/A

10. Performance Testing – (b) (4)
(b) (4)



(b) (4)

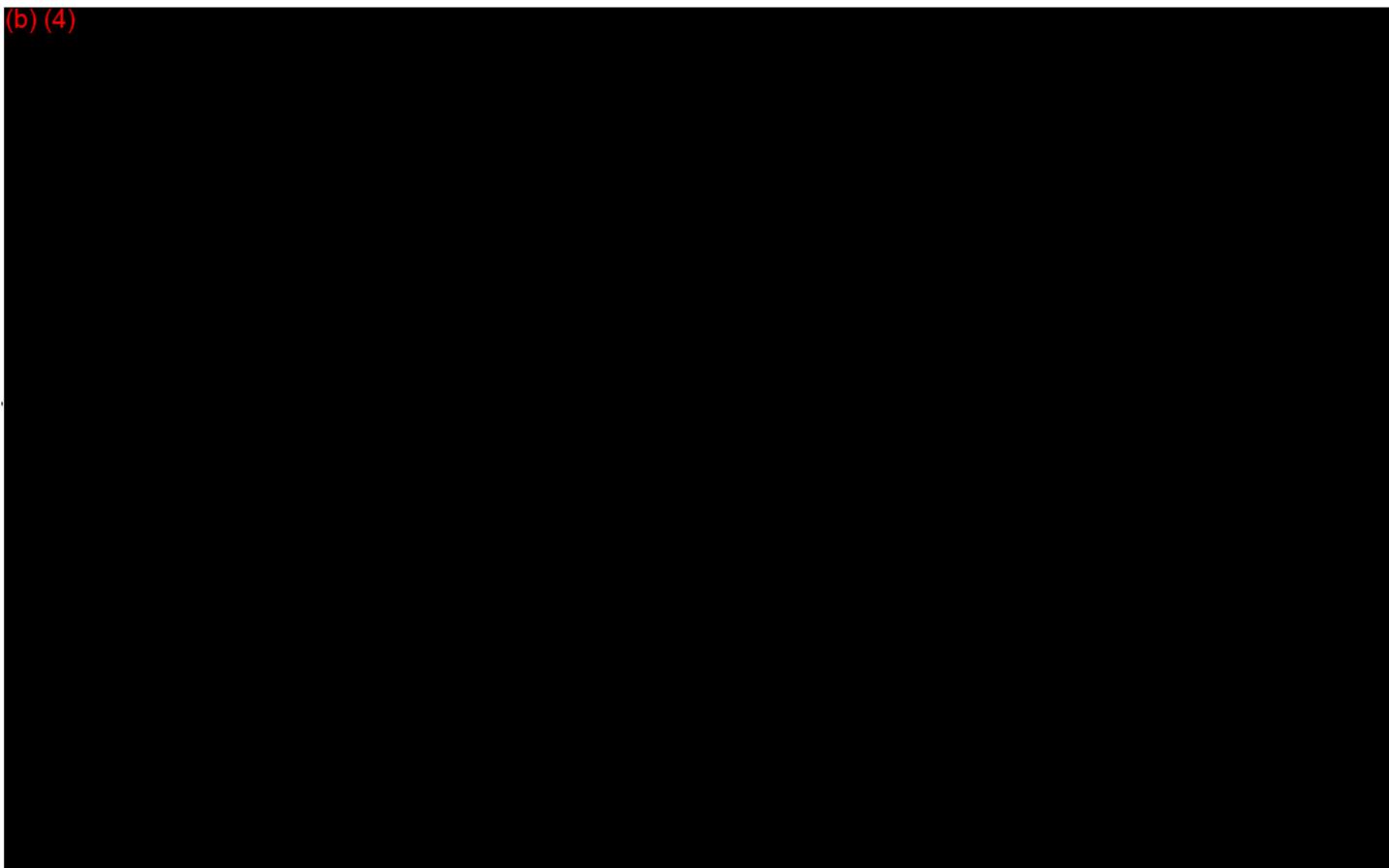


11. Performance Testing – (b) (4)

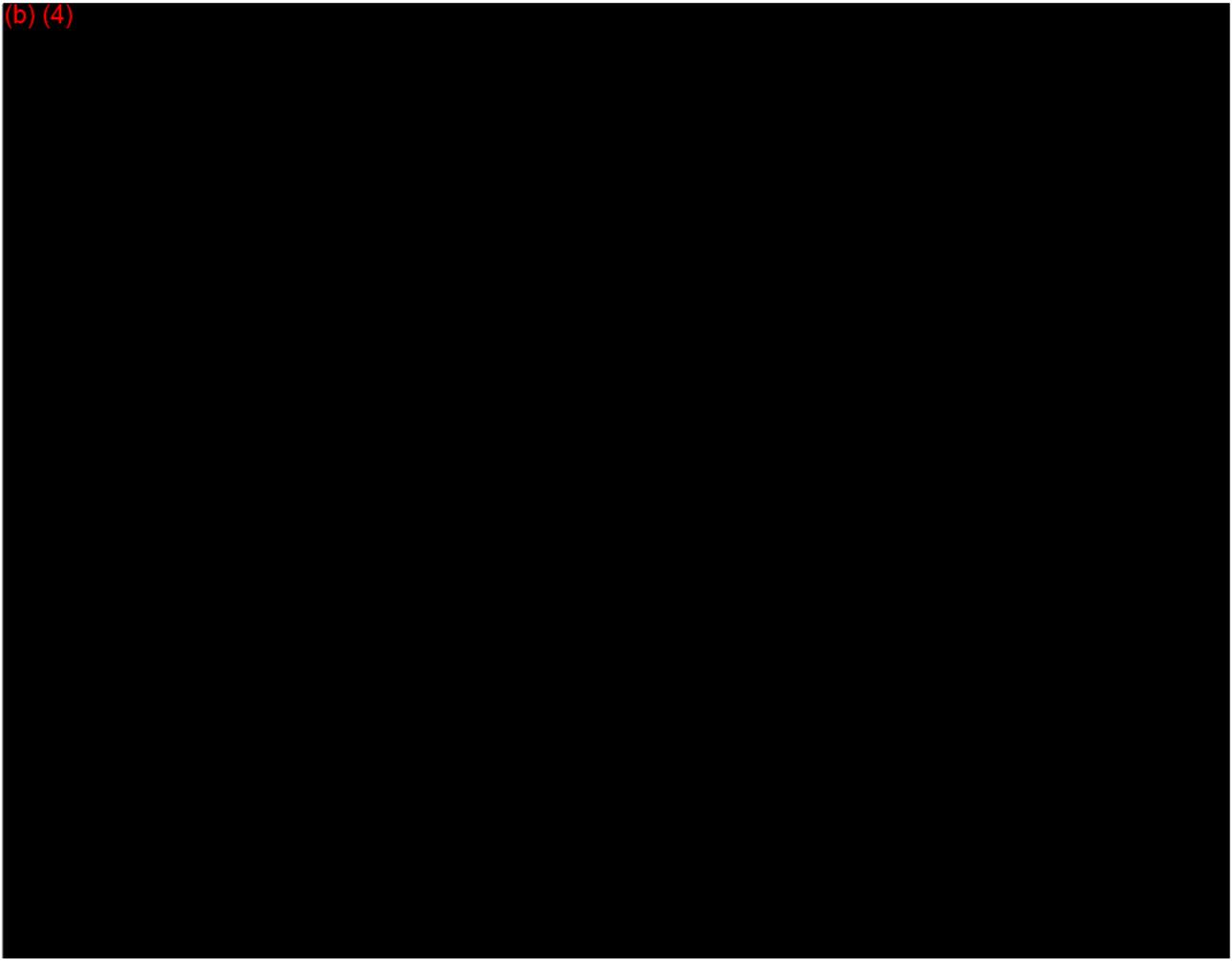
12. Performance Testing – (b) (4)

13. Sterilization/Shelf Life/Reuse

(b) (4)

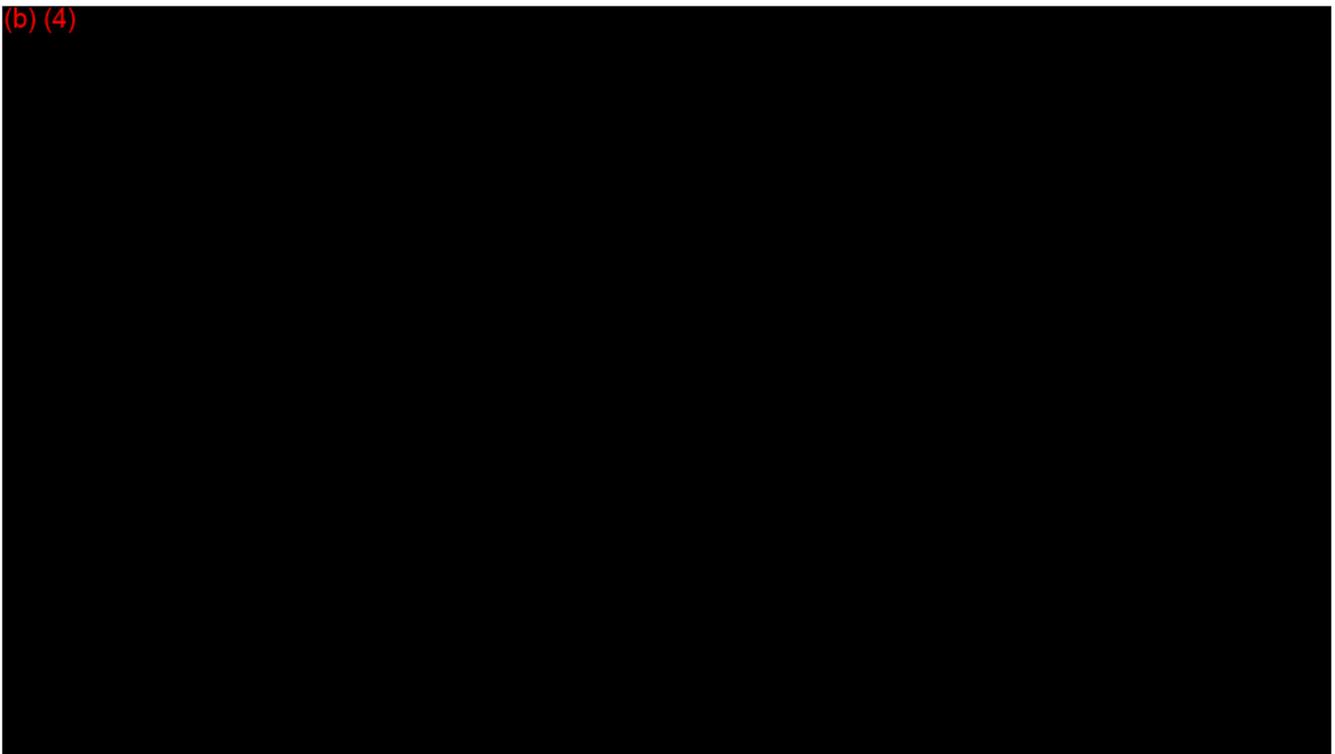


(b) (4)



14. Labeling

(b) (4)



(b) (4)

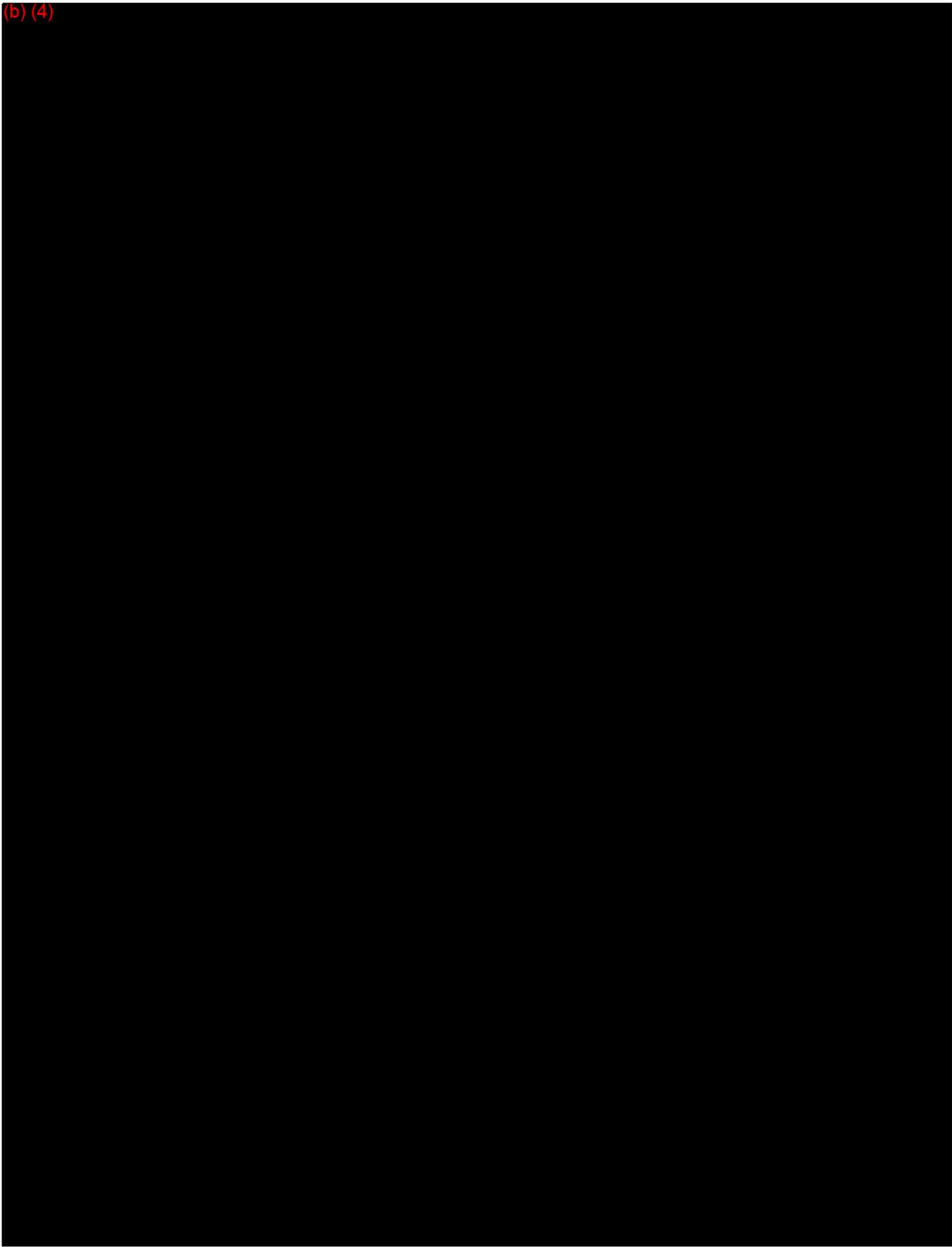
15. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	X		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NSE
3. Same Technological Characteristics?		X	If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?	X		If YES = Go To 6
5. Descriptive Characteristics Precise Enough?			If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?		X	If YES = Stop NSE
7. Accepted Scientific Methods Exist?	X		If NO = Stop NSE
8. Performance Data Available?	X		If NO = Request Data
9. Data Demonstrate Equivalence?	X		Final Decision: SE

Note: See

http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please

(b) (4)



(b) (4)



Lisa M. Lim
Lisa M. Lim, Ph.D., Biomedical Engineer

David Krause
David Krause, Ph.D., PRSB Branch Chief

10/26/07
Date

10/26/2007
Date

Lim, Lisa

From: Dustyn Webb [dustyn@cytoplast.com]
Sent: Friday, October 26, 2007 1:02 PM
To: Lim, Lisa
Subject: Re: K072076/S01
Attachments: 2-0 suture draft package label.pdf

Dr. Lim,

(b) (4)

Dustyn

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

From: Lim, Lisa
To: Dustyn Webb
Cc: Shane Shuttlesworth ; chad@cytoplast.com
Sent: Friday, October 26, 2007 9:44 AM
Subject: RE: K072076/S01

Sent again, as you requested.

From: Lim, Lisa
Sent: Friday, October 26, 2007 9:08 AM
To: 'Dustyn Webb'
Cc: Shane Shuttlesworth; chad@cytoplast.com
Subject: RE: K072076/S01

Dustyn,

(b) (4)

Lisa

From: Dustyn Webb [mailto:dustyn@cytoplast.com]
Sent: Thursday, October 25, 2007 4:42 PM
To: Lim, Lisa
Cc: Shane Shuttlesworth; chad@cytoplast.com
Subject: Re: K072076/S01

Dr. Lim,

(b) (4)


CYTOPLAST™
SIMPLE | PREDICTABLE | PRACTICAL

PTFE

WHITE MONOFILAMENT

NONABSORBABLE SUTURE

STERILE EO  

CS-0418 does not meet the USP knot-pull standard for a USP 2-0 surgical suture (1.38 kgf test value versus the 1.44 kgf standard).

CE 0120

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician or dentist.

2-0

Metric 3

18"/45 cm



C6

Reverse Cutting

3/8 Circle 18.7 mm

REF CS0418

LOT



OSTEOGENICS

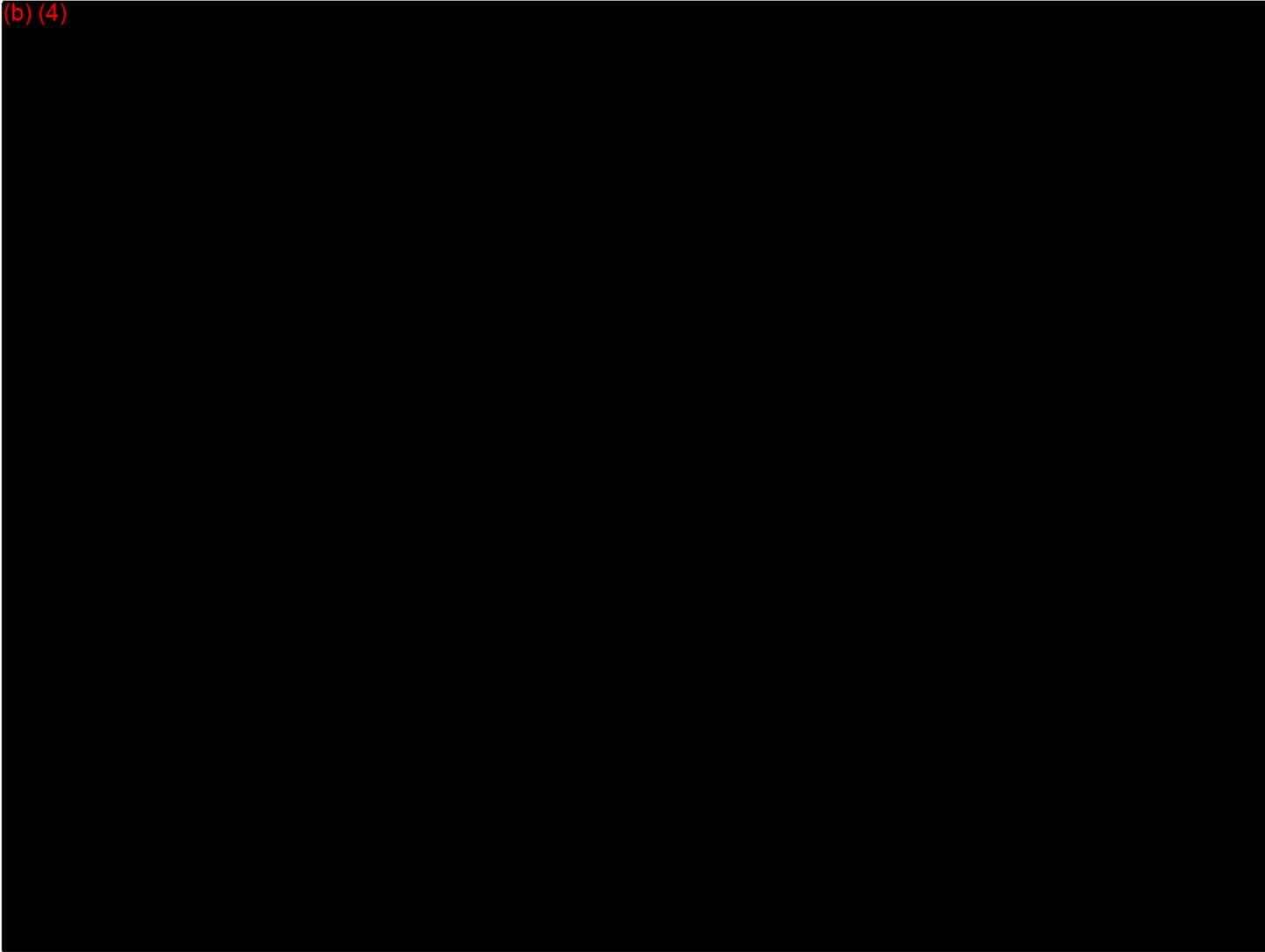
BIOMEDICAL
4620 71st Street, Bldg 78-79
Lubbock, Texas 79424 USA
888.796.1923
www.cytoplast.com

Lim, Lisa

From: Dustyn Webb [dustyn@cytoplast.com]
Sent: Wednesday, October 24, 2007 10:12 PM
To: Lim, Lisa
Cc: Shane Shuttlesworth
Subject: Re: K072076/S01
Attachments: Suture 510k--PND-Summary.pdf; FDA Premarket Notif 510(k) Intro.pdf; Suture IFU complete--10-24-07.doc

Lisa,

(b) (4)



Regards,

Dustyn

----- Original Message -----
From: Lim, Lisa

10/25/2007

21



Cytoplast® PTFE Suture
INSTRUCTIONS FOR USE

Description:

Cytoplast® PTFE Suture is a nonabsorbable, monofilament suture manufactured from 100% high-density polytetrafluoroethylene (PTFE) polymer, extruded in such a fashion as to produce a structure with a minimal pore size and volume while maintaining integrity and tensile strength. The suture is undyed and contains no additives. Cytoplast® PTFE Suture meets USP requirements, with the exception of CS-0418, which does not meet the USP knot-pull standard for a USP 2-0 surgical suture (1.38 kgf test value versus the 1.44 kgf standard).

Actions:

PTFE has been shown in clinical trials to elicit minimal tissue reaction. The Cytoplast® PTFE Suture is not absorbed or subject to weakening by tissue enzymes, and does not degrade in the presence of infection.

Indications:

The Cytoplast® PTFE Suture is indicated for use in all types of soft tissue approximation and/or ligation, including cardiovascular, dental and general surgeries, as well as repair of the dura mater. The device is not indicated for use in ophthalmic surgery, microsurgery and peripheral neural tissue.

Contraindications:

There are no known contraindications.

Warnings:

The safety and effectiveness of this suture in ophthalmic, microsurgical, and peripheral neural applications has not been established.

Tissue invasion of Cytoplast® PTFE Suture can result in attachment of the suture to the tissue it penetrates in long-term use. Such attachment may make removal of the suture difficult.

The device is for single use only. Do not resterilize.

Precautions:

Misuse of this suture, like any other suture, can result in severe injury or death to the patient. As with any suture, care should be taken to avoid damage when handling. Avoid crushing or crimping the suture with surgical instruments or exposing the suture to sharp edges. In order to minimize needle damage, do not grasp or drive the needle from near the channel where the suture is attached.

Knot security requires standard surgical techniques of flat and square ties with additional throws as indicated by surgical circumstances and the experience of the surgeon. When tying knots with the Cytoplast® PTFE Suture, tension should be applied by pulling each strand of the suture in opposite directions with equal force. Caution: this tension should not be applied by pulling on the needle itself, but is applied by grasping the suture with the fingers or surgical instruments. As the knot is tensioned, the air in the suture is forced out. Care should be taken to avoid using a jerking motion, which could break the suture or cause separation of the suture from the needle. Uneven tensioning of a well-formed square knot may result in an unsecure knot. When the Cytoplast® PTFE Suture is properly tensioned and formed, standard surgical knotting techniques will produce a secure knot.

Sterility:

Cytoplast® PTFE Suture is supplied STERILE unless the integrity of the package has been compromised. The device is for single use only. Do not resterilize.

Adverse Reactions:

None reported.

Dosages and Administration:

Use as required per surgical procedure.

How Supplied:

Cytoplast® PTFE Suture is available as sterile strands in a variety of sizes and lengths with permanently attached needles.

Caution:

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician or dentist.

LABELING SYMBOLS

Symbols may be used on package labeling for easy identification.

-  Use By
-  Do Not Reuse
-  Attention, see instructions for use
-  Method of Sterilization Using Ethylene Oxide
-  Lot Number
-  Catalog Number
-  Manufacturer
-  Authorized Representative in the European Community

 Osteogenics Biomedical, Inc.
4620 71st Street, Bldg 78-79
Lubbock, TX 79424 USA
Tel: 806-796-1923
Toll-free: 888-796-1923
www.cytoplast.com

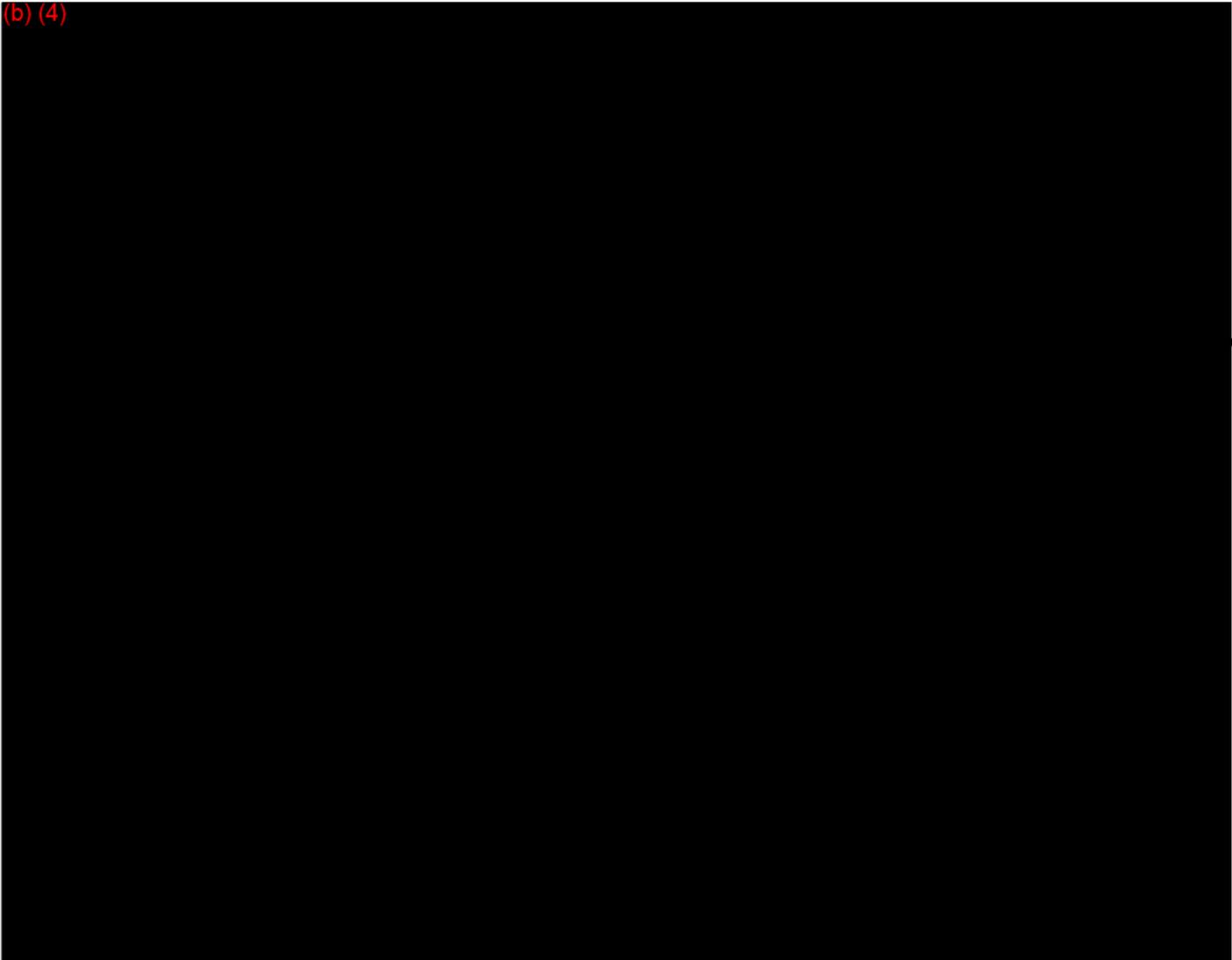
 Emergo Europe
Molenstraat 15
2513 BH, The Hague
The Netherlands

Revised 07/07

Lim, Lisa

From: Dustyn Webb [dustyn@cytoplast.com]
Sent: Thursday, October 25, 2007 4:42 PM
To: Lim, Lisa
Cc: Shane Shuttlesworth; chad@cytoplast.com
Subject: Re: K072076/S01
Attachments: Suture Comparison Table 10-25-07.doc

Dr. Lim,



Regards,

Dustyn Webb
Regulatory/Quality Manager
Osteogenics Biomedical, Inc.

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

| From: Lim, Lisa

10/26/2007

To: [Dustyn Webb](#)
Cc: [Shane Shuttlesworth](#)
Sent: Thursday, October 25, 2007 1:50 PM
Subject: RE: K072076/S01

Dustyn,

(b) (4)

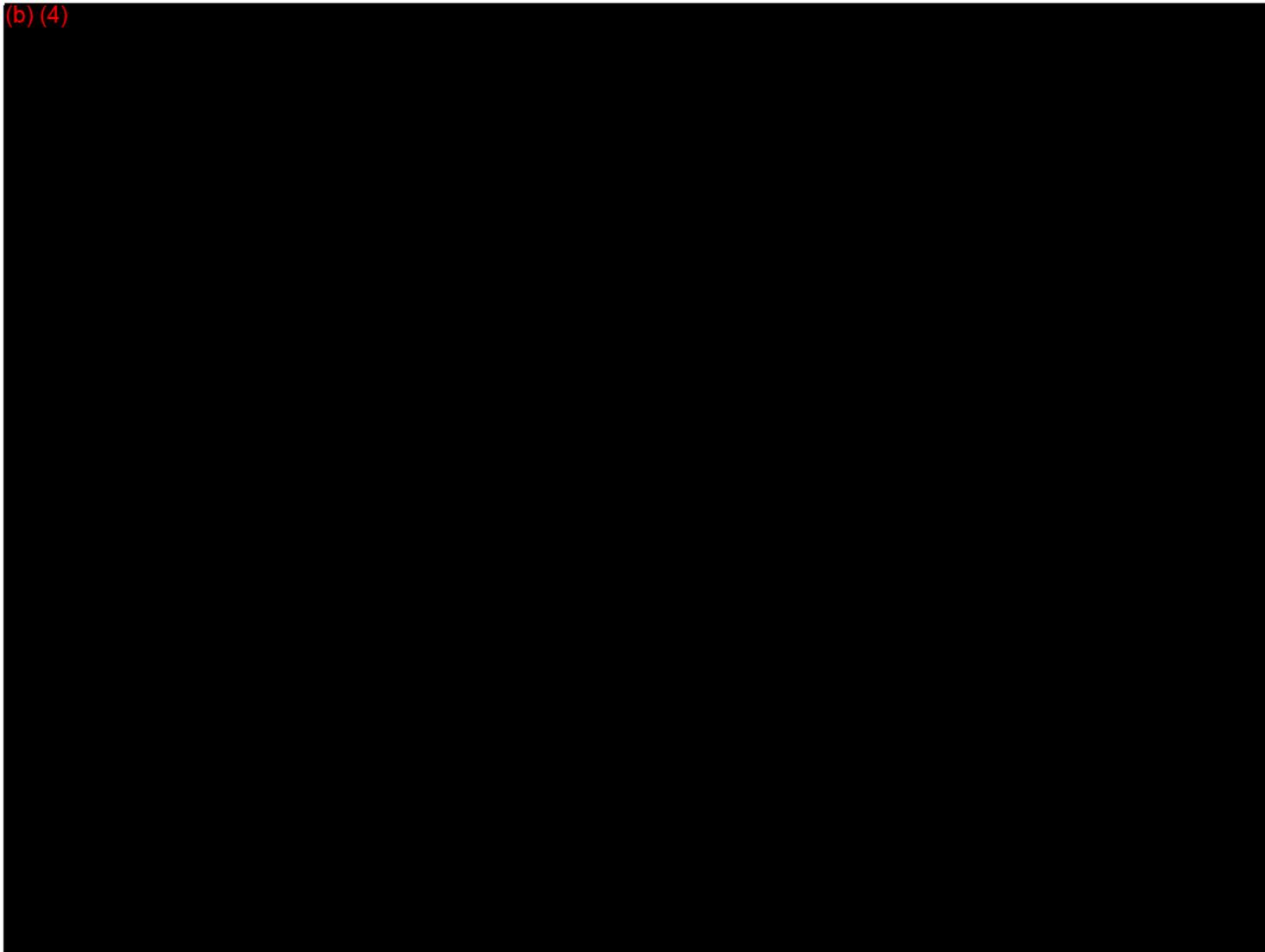
A large black rectangular redaction box covers the majority of the page content below the first email header.

Lisa

From: Dustyn Webb [mailto:dustyn@cytoplast.com]
Sent: Wednesday, October 24, 2007 10:12 PM
To: Lim, Lisa
Cc: Shane Shuttlesworth
Subject: Re: K072076/S01

Lisa,

(b) (4)

A very large black rectangular redaction box covers the entire lower half of the page, starting below the second email header and extending to the bottom margin.

Regards,

Dustyn

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

From: Lim, Lisa

To: Dustyn Webb

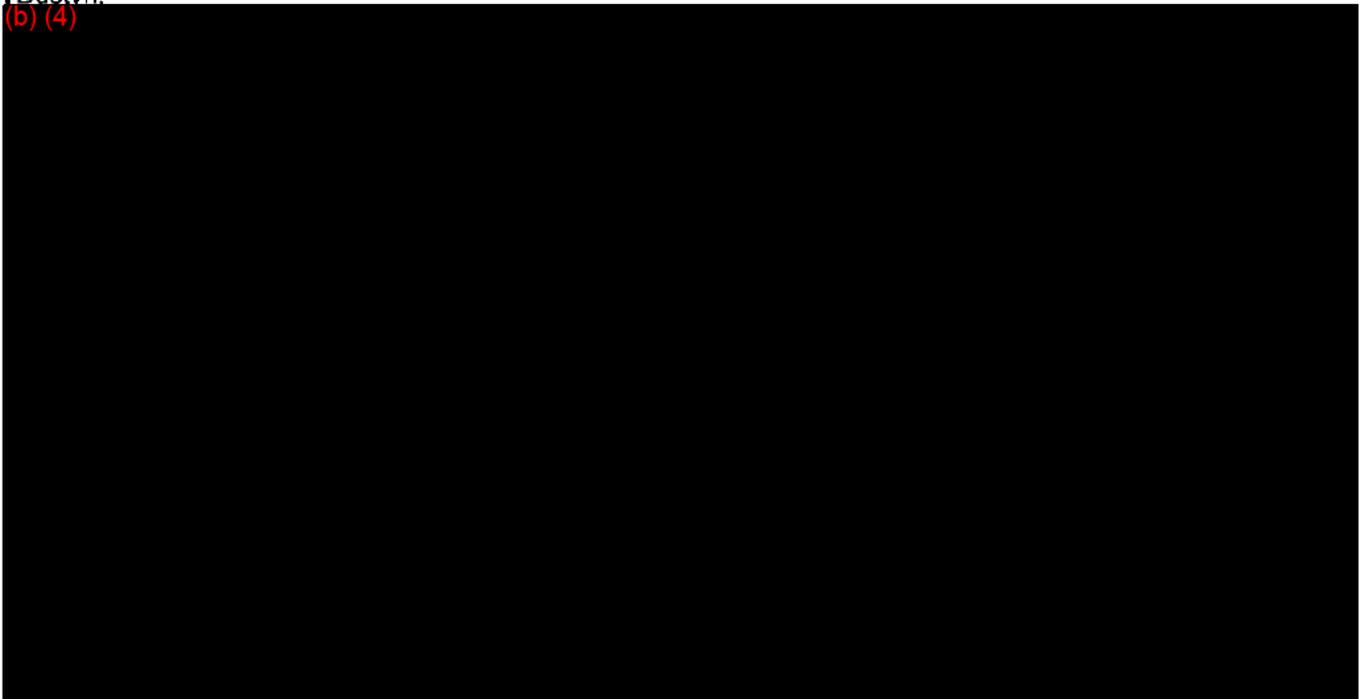
Cc: Shane Shuttlesworth ; chad@cytoplast.com

Sent: Wednesday, October 24, 2007 9:00 AM

Subject: RE: K072076/S01

Dustyn,

(b) (4)



Thanks,
Lisa

(b) (4)



Lim, Lisa

From: Dustyn Webb [dustyn@cytoplast.com]
Sent: Thursday, October 25, 2007 4:48 PM
To: Lim, Lisa
Subject: Fw: Suture test info.
Attachments: TP-032r4.pdf

Lisa,

See the attached controlled copy of our current suture properties testing vendor's diameter protocol.

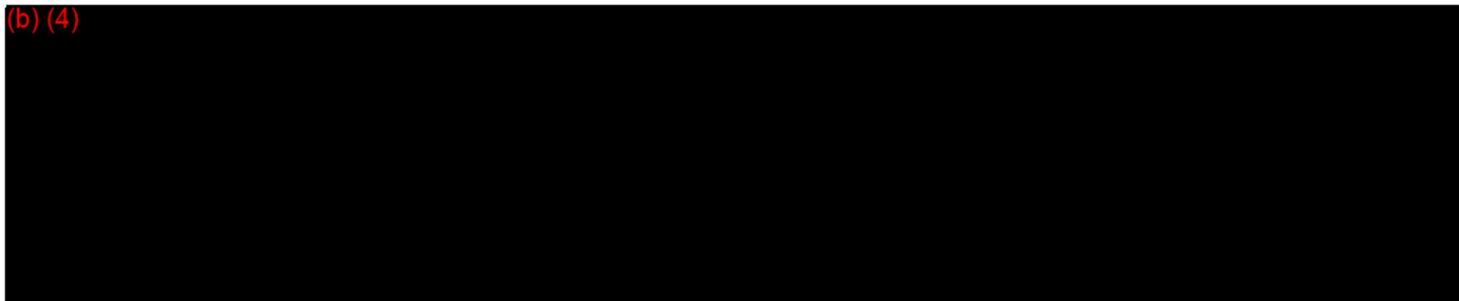
Dustyn

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

From: Knouse, Bob
To: dustyn@cytoplast.com
Sent: Thursday, October 25, 2007 2:00 PM
Subject: Suture test info.

Good Afternoon Dustyn,

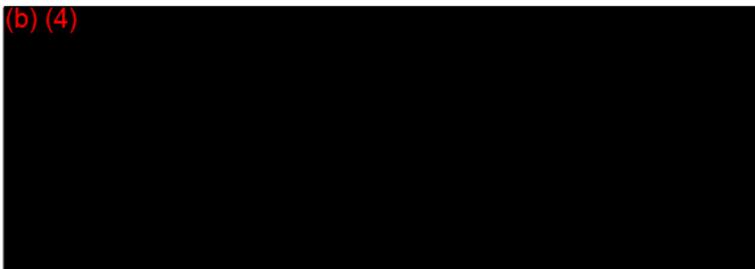
(b) (4)



Regards,

Bob

(b) (4)

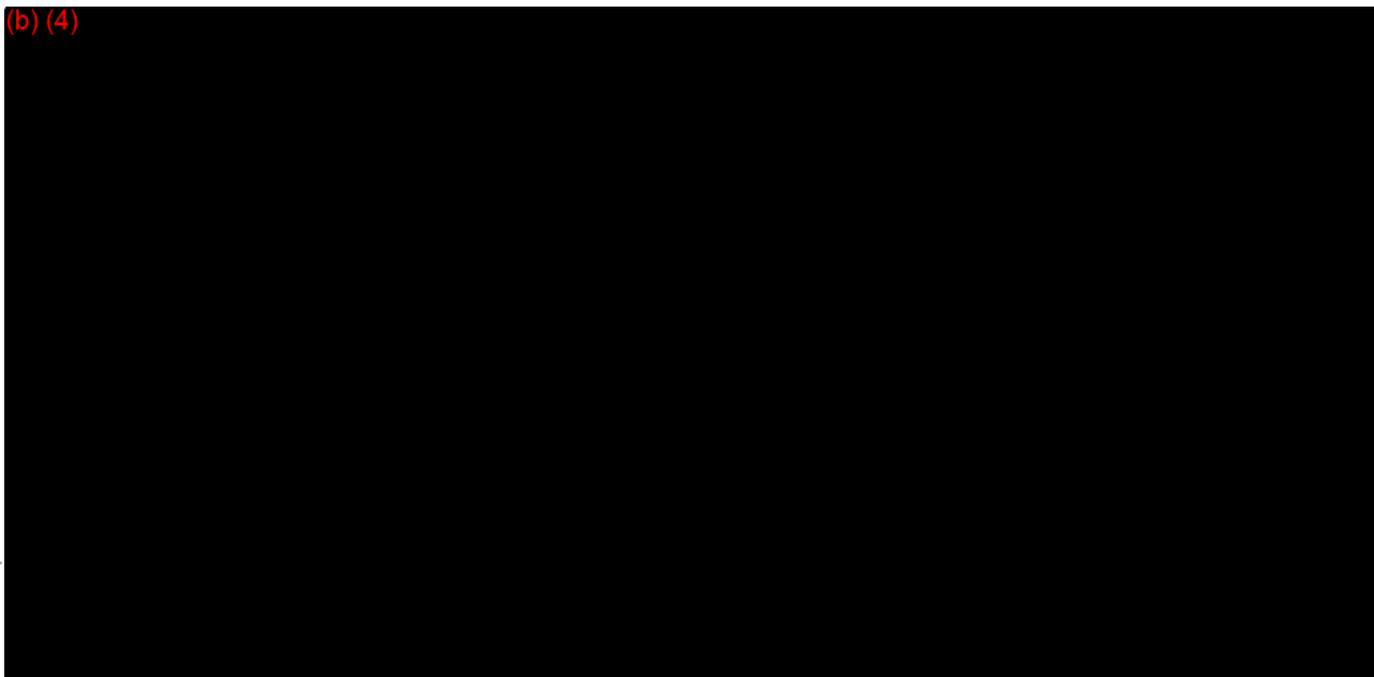


Lim, Lisa

From: Lim, Lisa
Sent: Wednesday, October 24, 2007 10:01 AM
To: 'Dustyn Webb'
Cc: Shane Shuttlesworth; chad@cytoplast.com
Subject: RE: K072076/S01

Dustyn,

(b) (4)

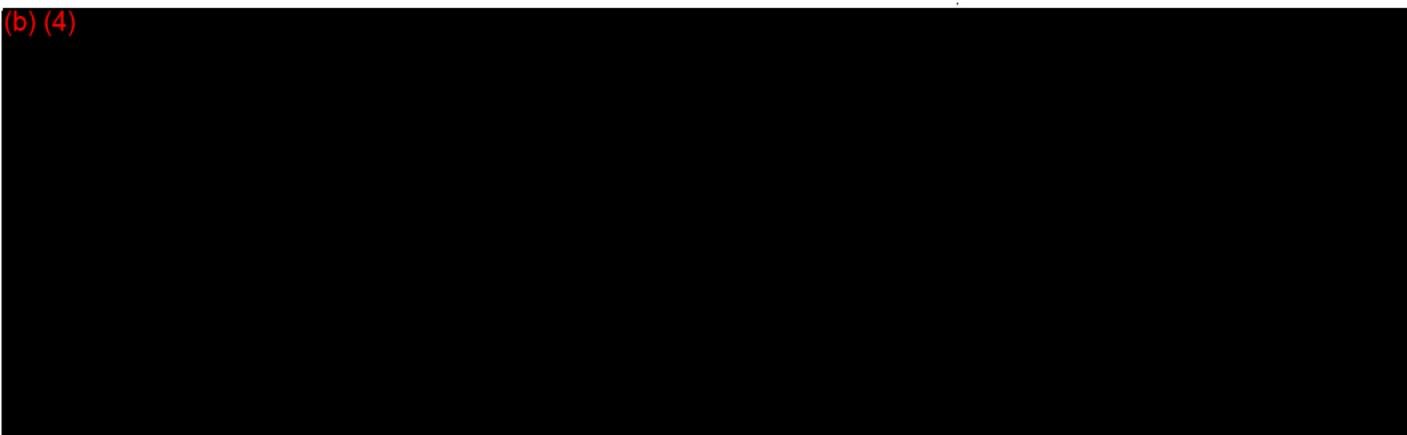


Thanks,
Lisa

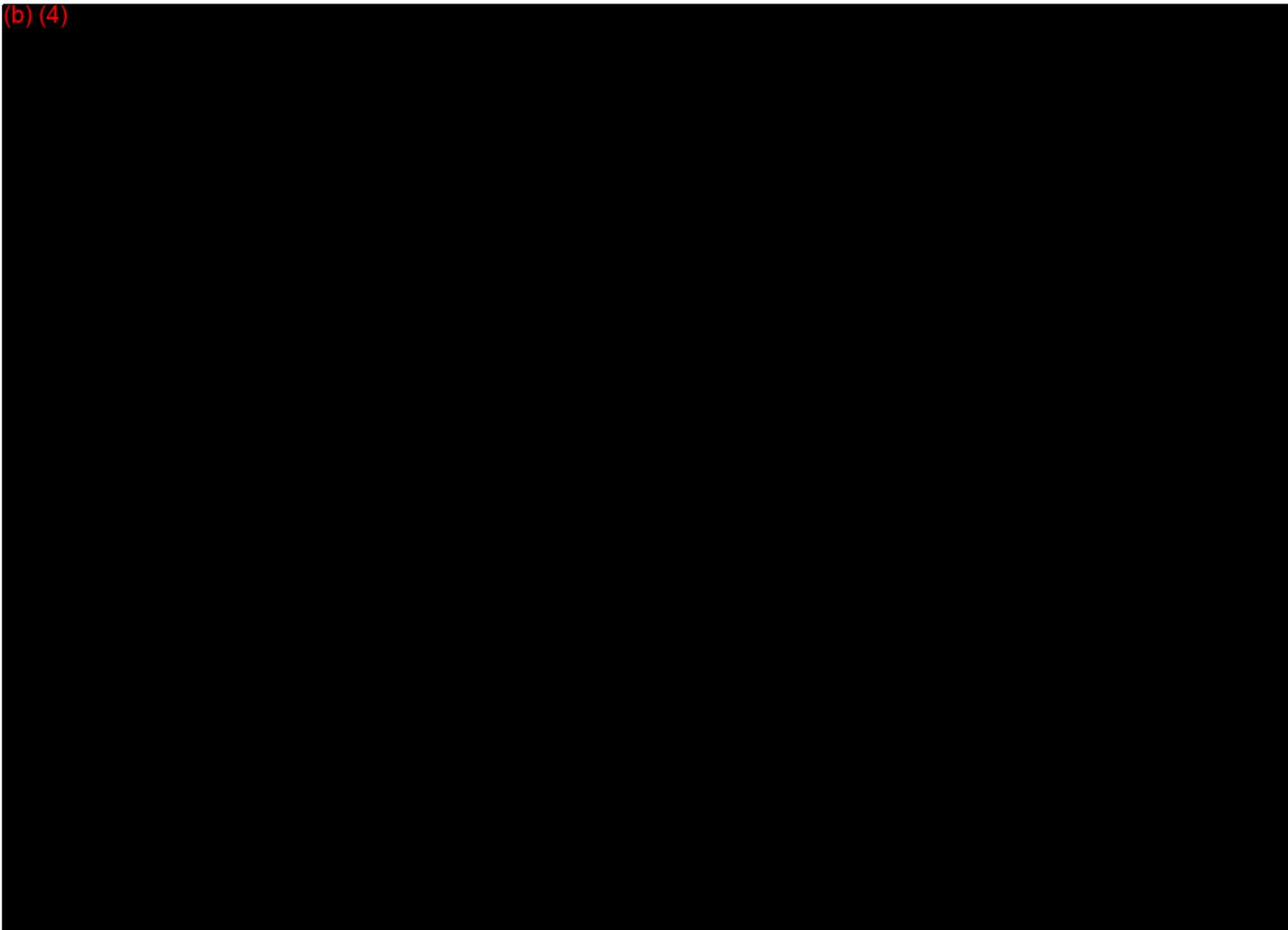
From: Dustyn Webb [mailto:dustyn@cytoplast.com]
Sent: Tuesday, October 23, 2007 2:36 PM
To: Lim, Lisa
Cc: Shane Shuttlesworth; chad@cytoplast.com
Subject: Re: K072076/S01

Lisa,

(b) (4)



(b) (4)



Regards,

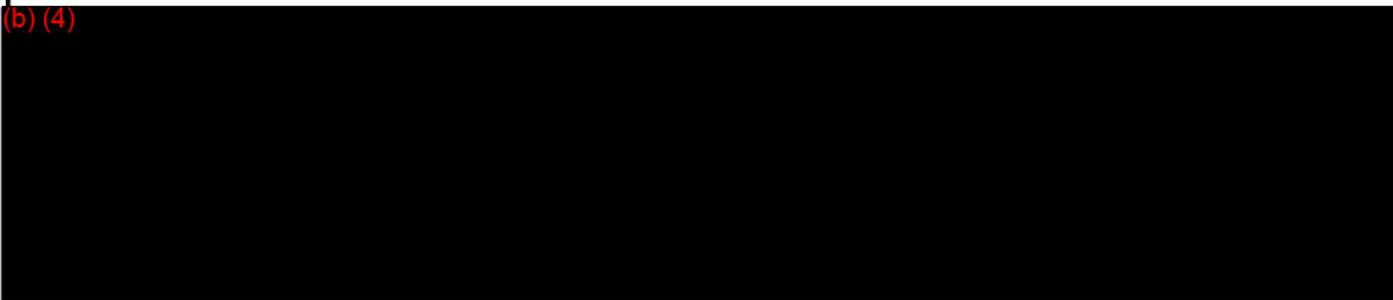
Dustyn Webb
Regulatory/Quality Manager
Osteogenics Biomedical, Inc.

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

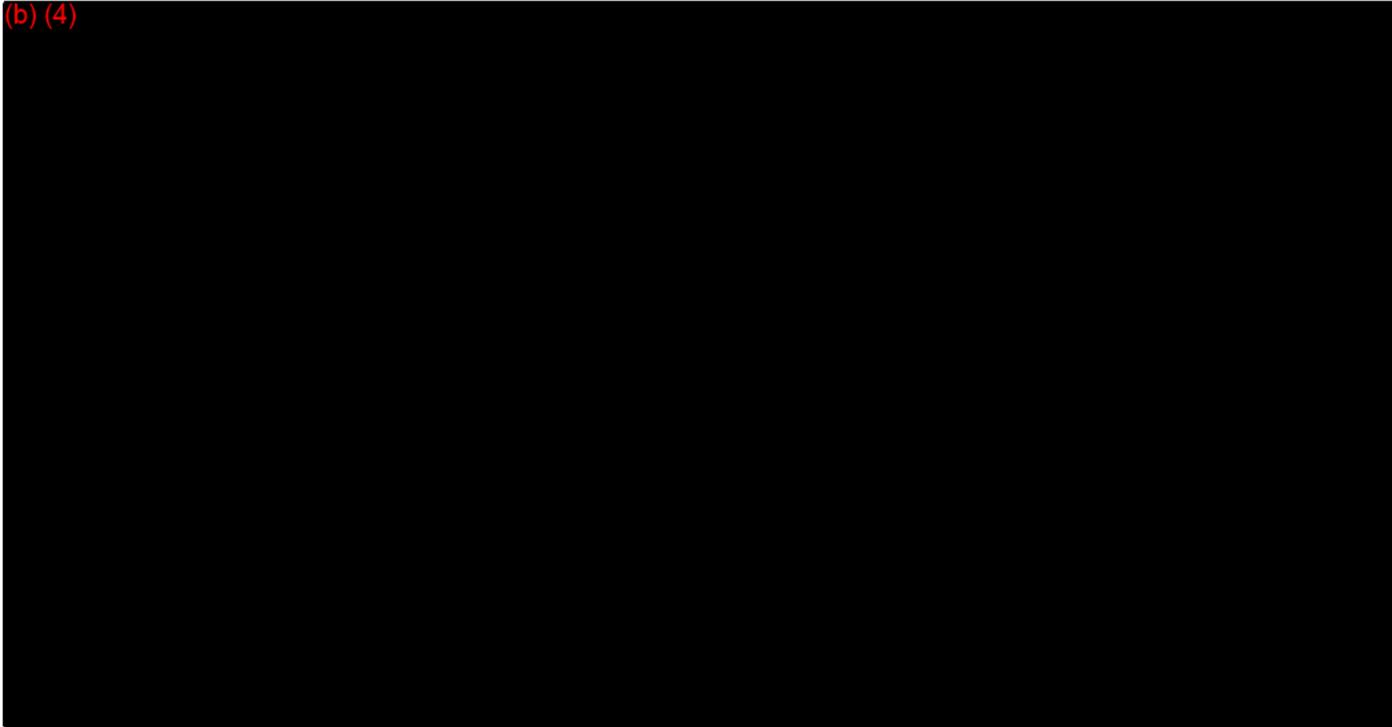
From: [Lim, Lisa](#)
To: [Dustyn Webb](#)
Sent: Tuesday, October 23, 2007 10:12 AM
Subject: K072076/S01

Dustyn,

(b) (4)



(b) (4)



Thanks,

Lisa

Lisa M. Lim, Ph.D.

Biomedical Engineer

Food & Drug Administration

Plastic & Reconstructive Surgery Devices Branch

9200 Corporate Blvd., HFZ-410

Rockville, MD 20850

(240) 276-3555 *New*

fax: (240) 276-3733 *New*

Lisa.Lim@fda.hhs.gov

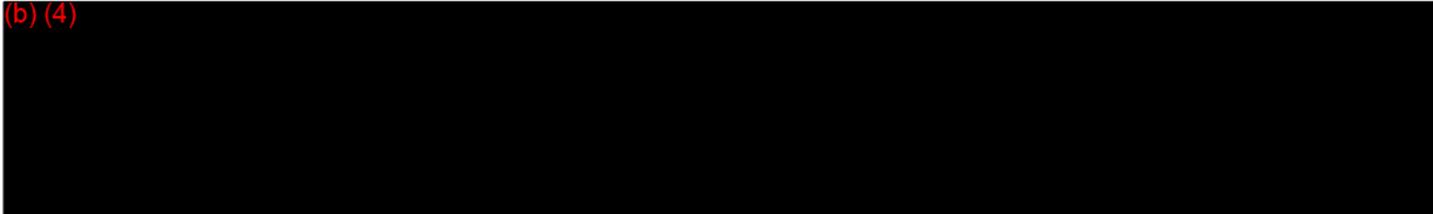
THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone.

Lim, Lisa

From: Dustyn Webb [dustyn@cytoplast.com]
Sent: Monday, October 22, 2007 4:14 PM
To: Lim, Lisa
Subject: K072076 - suture--Time 0 post-sterilization testing
Attachments: Suture 4-year Table - Oct 2007.doc; Suture Testing - DS-Time 0.pdf

Lisa,

(b) (4)



Best Regards,

Dustyn

Cytoplast Suture REF	USP Size	Diameter Limits (mm)	Time 0 Pre-Sterilization Cytoplast Knot-Pull Average (kgf)	Time 0 Post-Sterilization Cytoplast Knot-Pull Average (kgf)	4-Year AA Post-Sterilization Cytoplast Knot-Pull Average (kgf)	Time 0 Pre-Sterilization Cytoplast Needle Attachment Average (kgf)	Time 0 Post-Sterilization Cytoplast Needle Attachment Average (kgf)	4-Year AA Post-Sterilization Cytoplast Needle Attachment Average (kgf)
CS0618RC CS0618PREM CS0618PERIO	4-0	0.15- 0.199						
CS0518	3-0	0.20- 0.249						
CS0418	2-0	0.30- 0.349						

(b) (4)

4-Year Shelf Life Table

PRE-REVIEW FORM: COMPANY/DEVICE HISTORY

Please complete the pre-review form prior to beginning the review of this 510(k). This form is designed to be a tool to identify key items that may be important to consider regarding the regulation of the subject device and if you should even begin the review of the 510(k).

If you answer YES to questions 1, 2 or 3; do NOT begin the review of this 510(k):	YES	NO
1. Are you aware of the submitter being the subject of an integrity investigation? (Please see <u>H:\INTEGRITY LIST\CDRH REVIEWER SCREENING LIST.DOC</u>)		✓
2. Is the device exempt from 510(k) by regulation (Please see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4134/510(K)%20EXEMPT%20%20FORM.DOC or subject to enforcement discretion (No regulation - See 510(k) Staff)?)		✓
3. Does this device type require a PMA by regulation? (Please see management.)		✓
Questions 4-8 are intended to help you start your review:	YES	NO
4. Is this 510(k) a candidate for "Refuse to Accept"? (If so, please use the Traditional/Abbreviated or Special 510(k) Refuse to Accept Screening Checklist, http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4d69/Screening%20Checklist.doc)		✓
5. a. Did the firm request expedited review? (See management.) b. Was expedited review granted? (See <i>Guidance for Industry and FDA Staff: Expedited Review of Devices for Premarket Submissions</i> , http://www.fda.gov/cdrh/mdufma/guidance/108.html)		✓
		✓
6. To the best of your knowledge, was there a pre-IDE, 513(g) or other pre-submission for this type of device?	Please list document number and/or date, here:	✓
7. To the best of your knowledge, has a 510(k) previously been submitted for this specific device (i.e., previously found NSE or withdrawn)?	Please list document number, here:	✓
8. Does this device have indications or technology that are cross-cutting and impact the review policy of another branch(es)? (Please contact other branch(es) and see <i>Guidance for Industry and FDA Staff on Bundling Multiple Devices or Multiple Indications in a Single Submission</i> http://www.fda.gov/cdrh/mdufma/guidance/1215.html)		✓



Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Abbreviated

K072076

Date: September 28, 2007
To: The Record
From: Lisa M. Lim, Ph.D.

Office: ODE
Division: DGRND

510(k) Holder: Osteogenics Biomedical, Inc.
Device Name: Cytoplast PTFE Suture
Contact: Dustyn Webb, Regulatory/Quality Manager
Phone: (806) 796-1923
Fax: (806) 796-0059
Email: dustyn@cytoplast.com

1. Recommendation: AI

Regulation Number: 21 CFR 878.5035
Regulation Name: Suture, surgical, nonabsorbable, expanded, polytetrafluoroethylene
Regulatory Class: Class II
Product Code: NBY

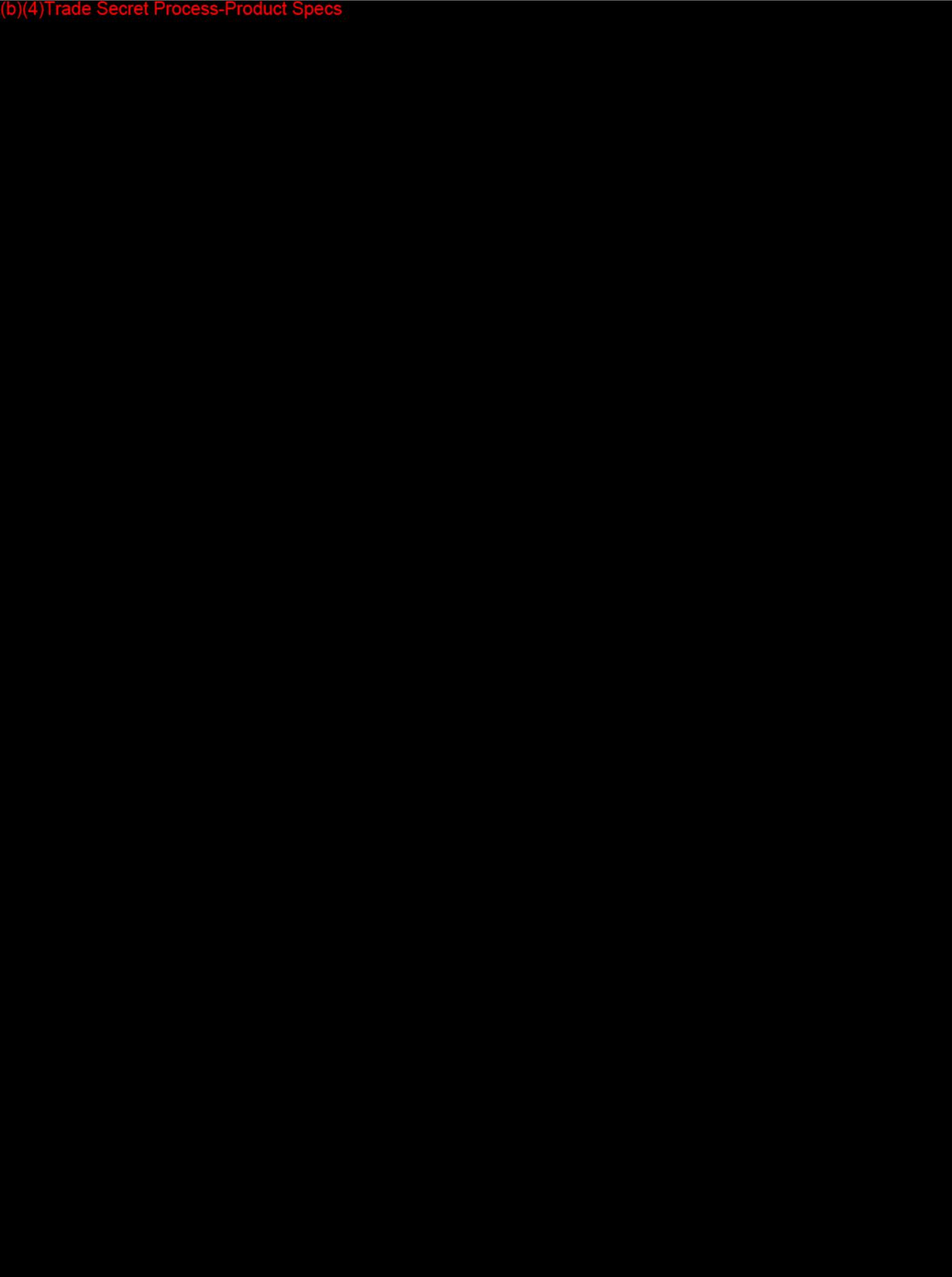
2. Purpose and Submission Summary

K072076 (dated July 25, 2007 and received July 30, 2007) was assigned to me on August 7, 2007 and is due to PRSB on September 28, 2007. This 510(k) involves an ePTFE suture previously cleared for soft tissue approximation in the oral cavity. In this application, the sponsor would like to market the device with an expanded indications for use, a new manufacturing site, a sterilization process change and a labeling change.

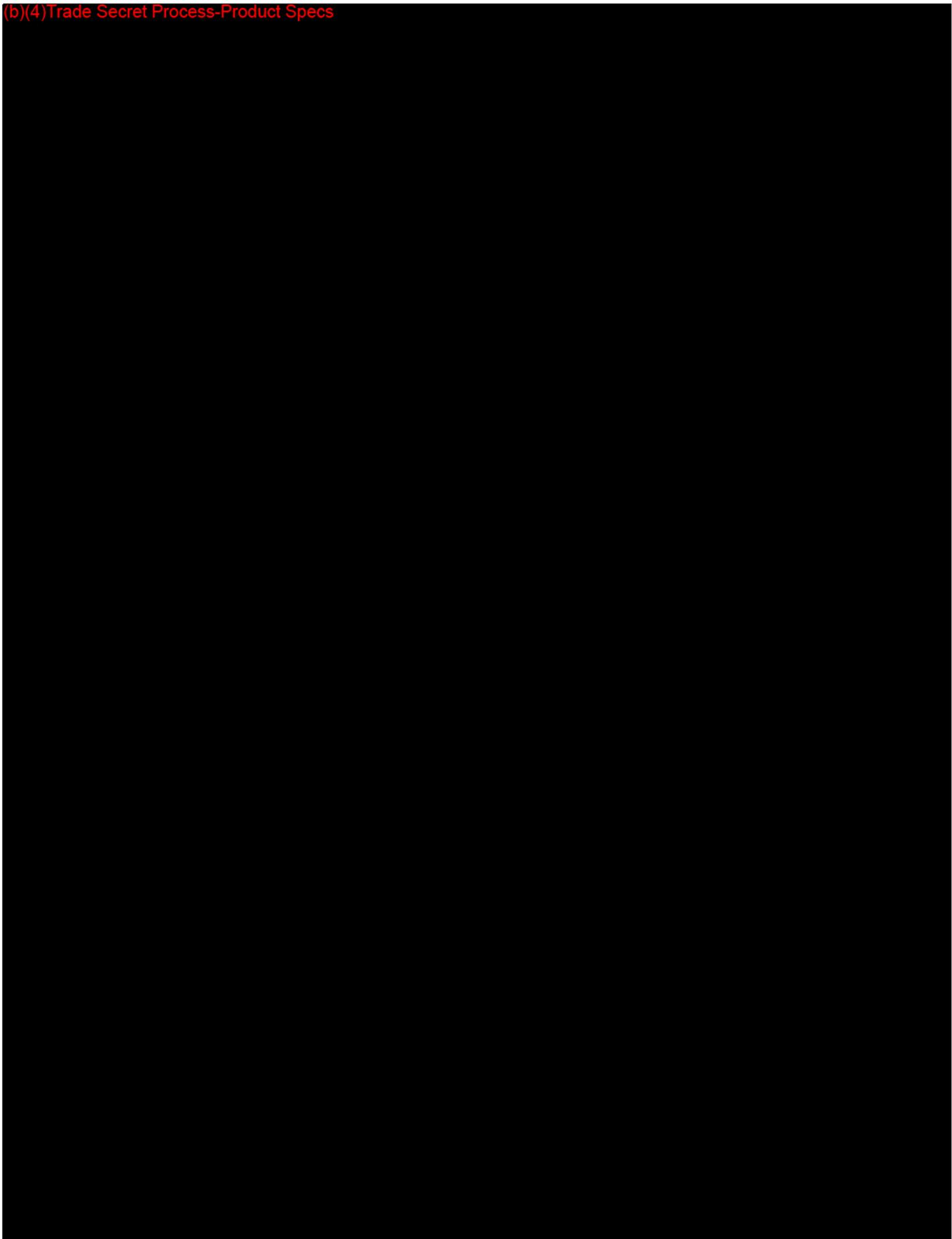
3. Administrative Requirements

Table with 4 columns: Requirement, Yes, No, N/A. Rows include: Indications for Use page, Truthful and Accuracy Statement, 510(k) Statement, Standards Form.

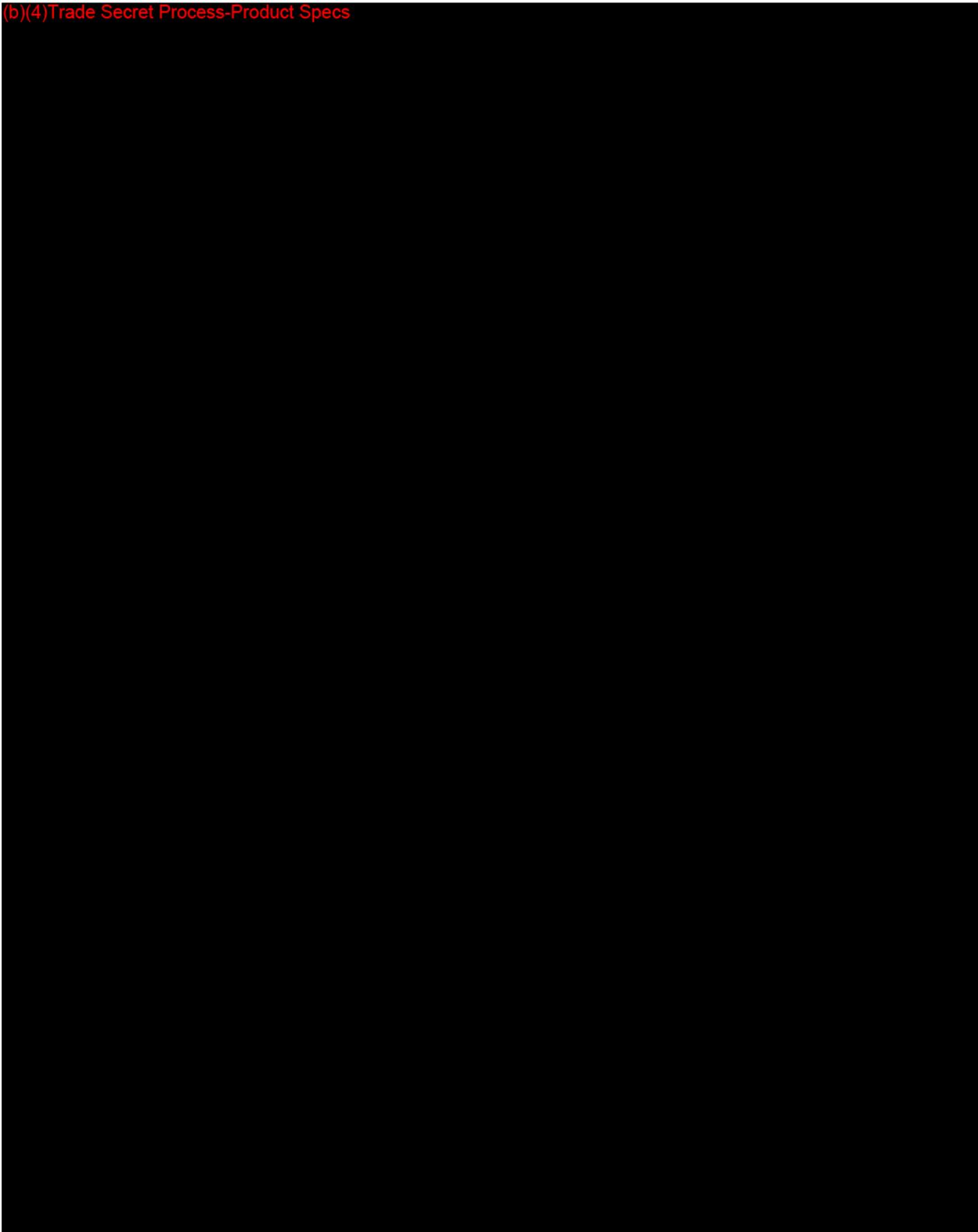
(b)(4)Trade Secret Process-Product Specs



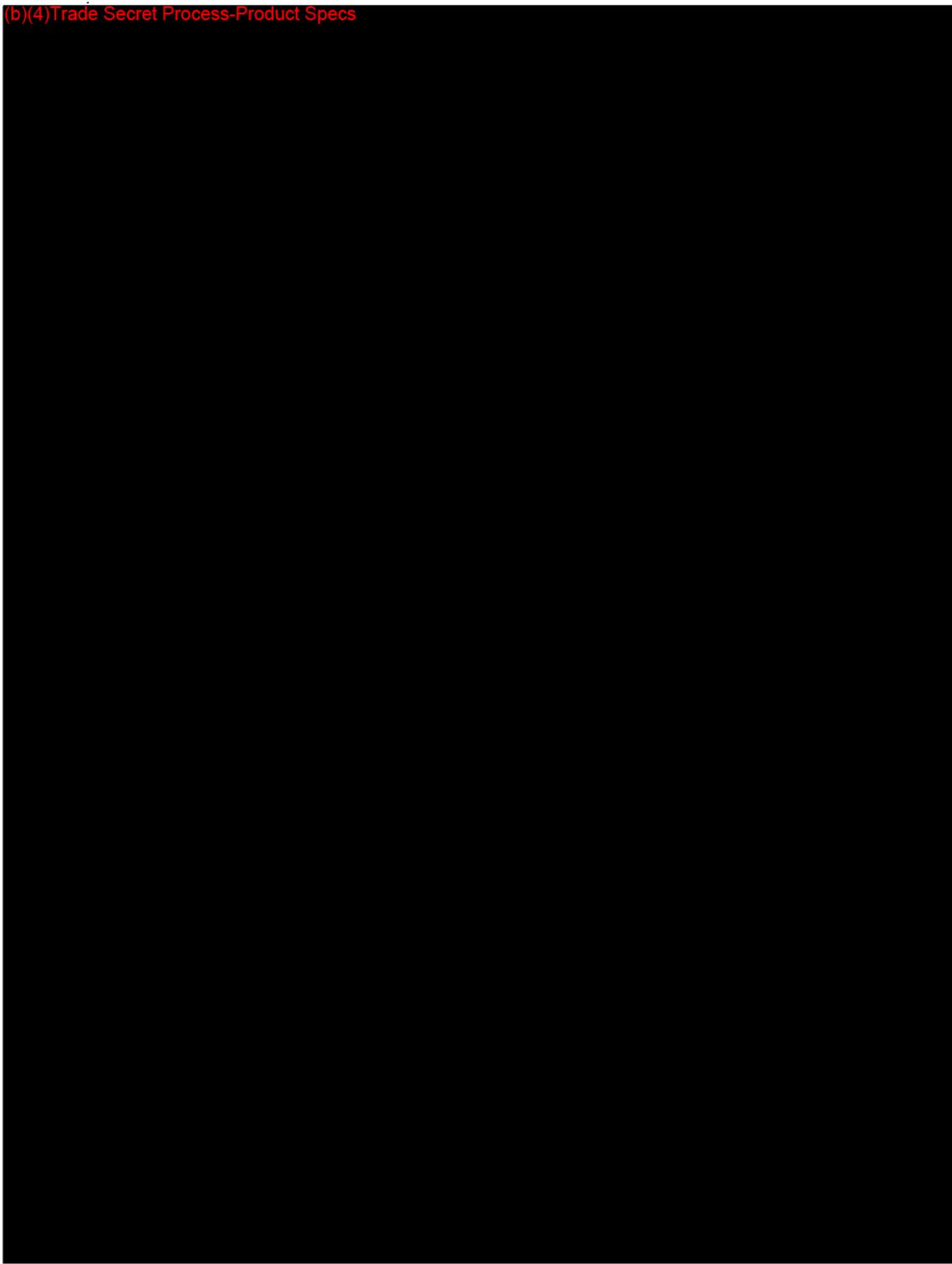
(b)(4)Trade Secret Process-Product Specs



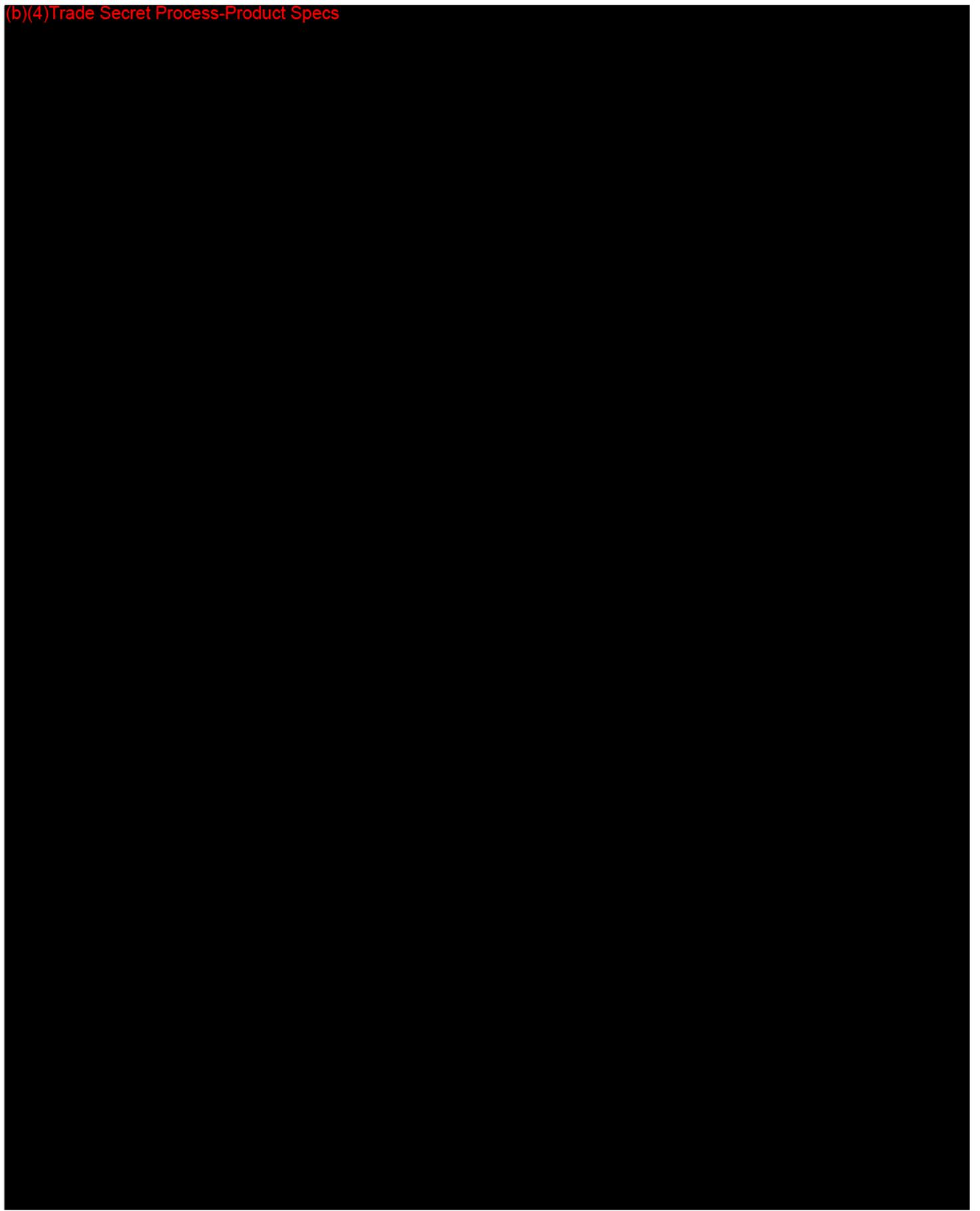
(b)(4)Trade Secret Process-Product Specs



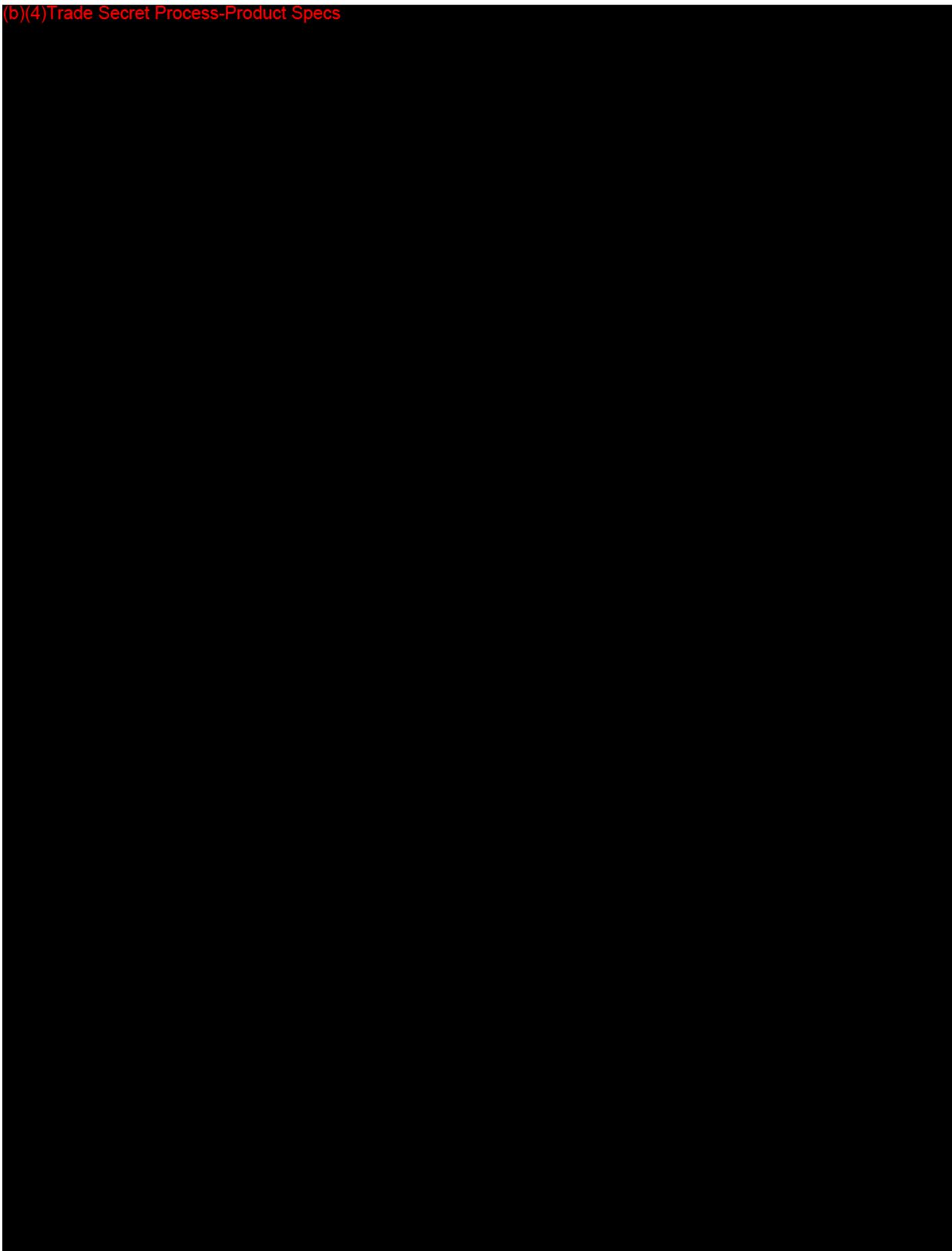
(b)(4) Trade Secret Process-Product Specs



(b)(4)Trade Secret Process-Product Specs



(b)(4)Trade Secret Process-Product Specs





Lisa M. Lim

Lisa M. Lim, Ph.D., Biomedical Engineer

David Krause

David Krause, Ph.D., PRSB Branch Chief

9/28/07

Date

9/28/07

Date

Lim, Lisa

From: Dustyn Webb [dustyn@cytoplast.com]
Sent: Thursday, September 27, 2007 3:05 PM
To: Lim, Lisa
Subject: Re: K072076 - IFU modifications
Attachments: Suture IFU - 9-27-07.doc

Lisa,

(b) (4)

Dustyn

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

From: Lim, Lisa
To: Dustyn Webb
Sent: Thursday, September 27, 2007 1:45 PM
Subject: RE: K072076 - IFU modifications

Dustyn,

(b) (4)

Thanks,
Lisa

From: Dustyn Webb [mailto:dustyn@cytoplast.com]
Sent: Thursday, September 27, 2007 1:41 PM
To: Lim, Lisa
Subject: K072076 - IFU modifications

Lisa,

(b) (4)

Best Regards,

Dustyn Webb
Osteogenics Biomedical



Cytoplast® PTFE Suture
INSTRUCTIONS FOR USE

Description:

Cytoplast® PTFE Suture is a nonabsorbable, monofilament suture manufactured from 100% high-density polytetrafluoroethylene (PTFE) polymer, extruded in such a fashion as to produce a structure with a minimal pore size and volume while maintaining integrity and tensile strength. The suture is undyed and contains no additives. Cytoplast® PTFE Suture meets USP requirements.

Actions:

PTFE has been shown in clinical trials to elicit minimal tissue reaction. The Cytoplast® PTFE Suture is not absorbed or subject to weakening by tissue enzymes, and does not degrade in the presence of infection.

Indications:

The Cytoplast® PTFE Suture is indicated for use in all types of soft tissue approximation and/or ligation, including cardiovascular, dental and general surgeries, as well as repair of the dura mater. The device is not indicated for use in ophthalmic surgery, microsurgery and peripheral neural tissue.

Contraindications:

There are no known contraindications.

Warnings:

The safety and effectiveness of this suture in ophthalmic, microsurgical, and peripheral neural applications has not been established.

Tissue invasion of Cytoplast® PTFE Suture can result in attachment of the suture to the tissue it penetrates in long-term use. Such attachment may make removal of the suture difficult.

The device is for single use only. Do not resterilize.

Precautions:

Misuse of this suture, like any other suture, can result in severe injury or death to the patient. As with any suture, care should be taken to avoid damage when handling. Avoid crushing or crimping the suture with surgical instruments or exposing the suture to sharp edges. In order to minimize needle damage, do not grasp or drive the needle from near the channel where the suture is attached.

Knot security requires standard surgical techniques of flat and square ties with additional throws as indicated by surgical circumstances and the experience of the surgeon. When tying knots with the Cytoplast® PTFE Suture, tension should be applied by pulling each strand of the suture in opposite directions with equal force.

Caution: this tension should not be applied by pulling on the needle itself, but is applied by grasping the suture with the fingers or surgical instruments. As the knot is tensioned, the air in the suture is forced out. Care should be taken to avoid using a jerking motion, which could break the suture or cause separation of the suture from the needle. Uneven tensioning of a well-formed square knot may result in an unsecure knot. When the Cytoplast® PTFE Suture is properly tensioned and formed, standard surgical knotting techniques will produce a secure knot.

Sterility:

Cytoplast® PTFE Suture is supplied STERILE unless the integrity of the package has been compromised. The device is for single use only. Do not resterilize.

Adverse Reactions:

Potential adverse effects associated with the use of any suture include: wound dehiscence, infection and localized transitory inflammatory reaction.

Dosages and Administration:

Use as required per surgical procedure.

How Supplied:

Cytoplast® PTFE Suture is available as sterile strands in a variety of sizes and lengths with permanently attached needles.

Caution:

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician or dentist.

LABELING SYMBOLS

Symbols may be used on package labeling for easy identification.

-  Use By
-  Do Not Reuse
-  Attention, see instructions for use
-  Method of Sterilization Using Ethylene Oxide
-  Lot Number
-  Catalog Number
-  Manufacturer
-  Authorized Representative in the European Community

 Osteogenics Biomedical, Inc.
4620 71st Street, Bldg 78-79
Lubbock, TX 79424 USA
Tel: 806-796-1923
Toll-free: 888-796-1923
www.cytoplast.com

 Emergo Europe
Molenstraat 15
2513 BH, The Hague
The Netherlands

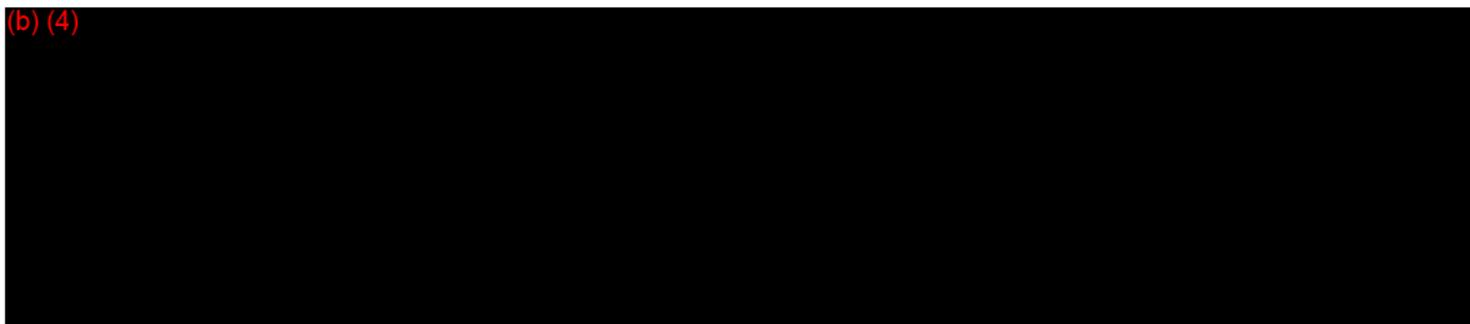
Revised 07/07

Lim, Lisa

From: Lim, Lisa
Sent: Thursday, September 27, 2007 11:17 AM
To: 'Dustyn Webb'
Subject: RE: K072076 - endotoxin test - LAL guidance document?

Dustyn,

(b) (4)

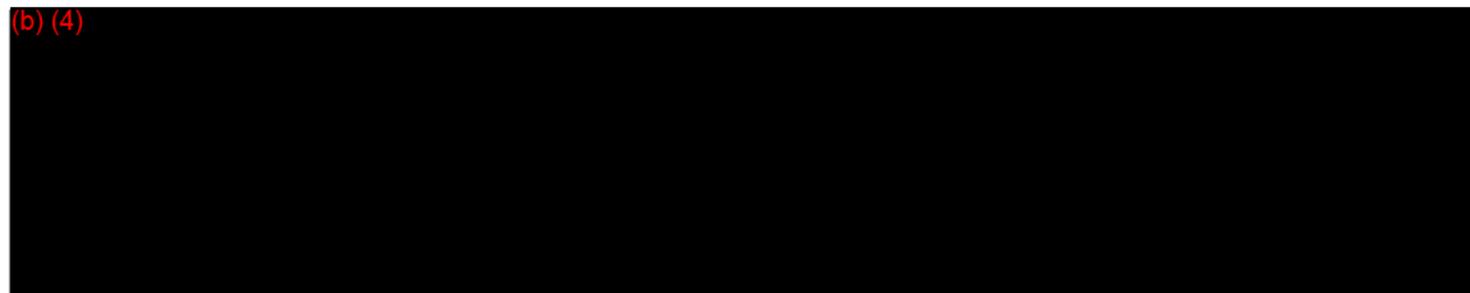


Thanks,
Lisa

From: Dustyn Webb [mailto:dustyn@cytoplast.com]
Sent: Thursday, September 27, 2007 11:07 AM
To: Lim, Lisa
Subject: K072076 - endotoxin test - LAL guidance document?

Lisa,

(b) (4)



Dustyn

Lim, Lisa

From: Lim, Lisa
Sent: Wednesday, September 26, 2007 8:59 AM
To: 'Dustyn Webb'
Subject: RE: K072076
Attachments: INDICATIONS FOR USE FORM ODE REVISED.DOC

Dustyn,

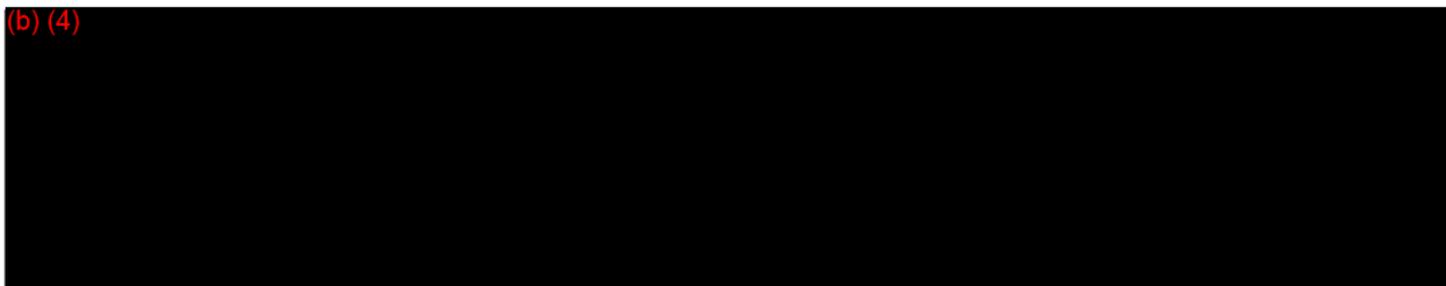
Sorry, in my haste to send you the email I forgot to send the attachment. Here it is.

Thanks,
Lisa

From: Dustyn Webb [mailto:dustyn@cytoplast.com]
Sent: Tuesday, September 25, 2007 5:35 PM
To: Lim, Lisa
Subject: Re: K072076

Lisa,

(b) (4)



Best Regards,

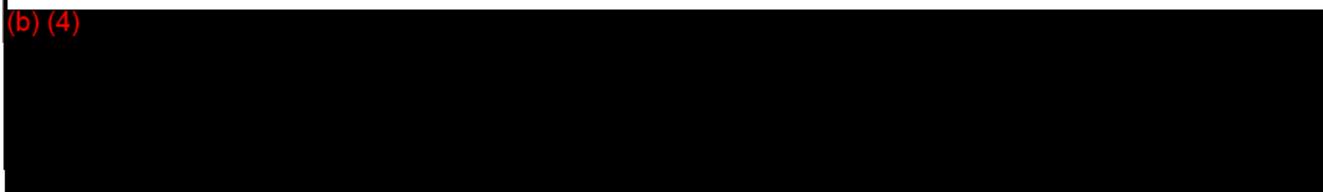
Dustyn Webb
Regulatory/Quality Manager
Osteogenics Biomedical, Inc.
(806)796-1923
dustyn@cytoplast.com

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

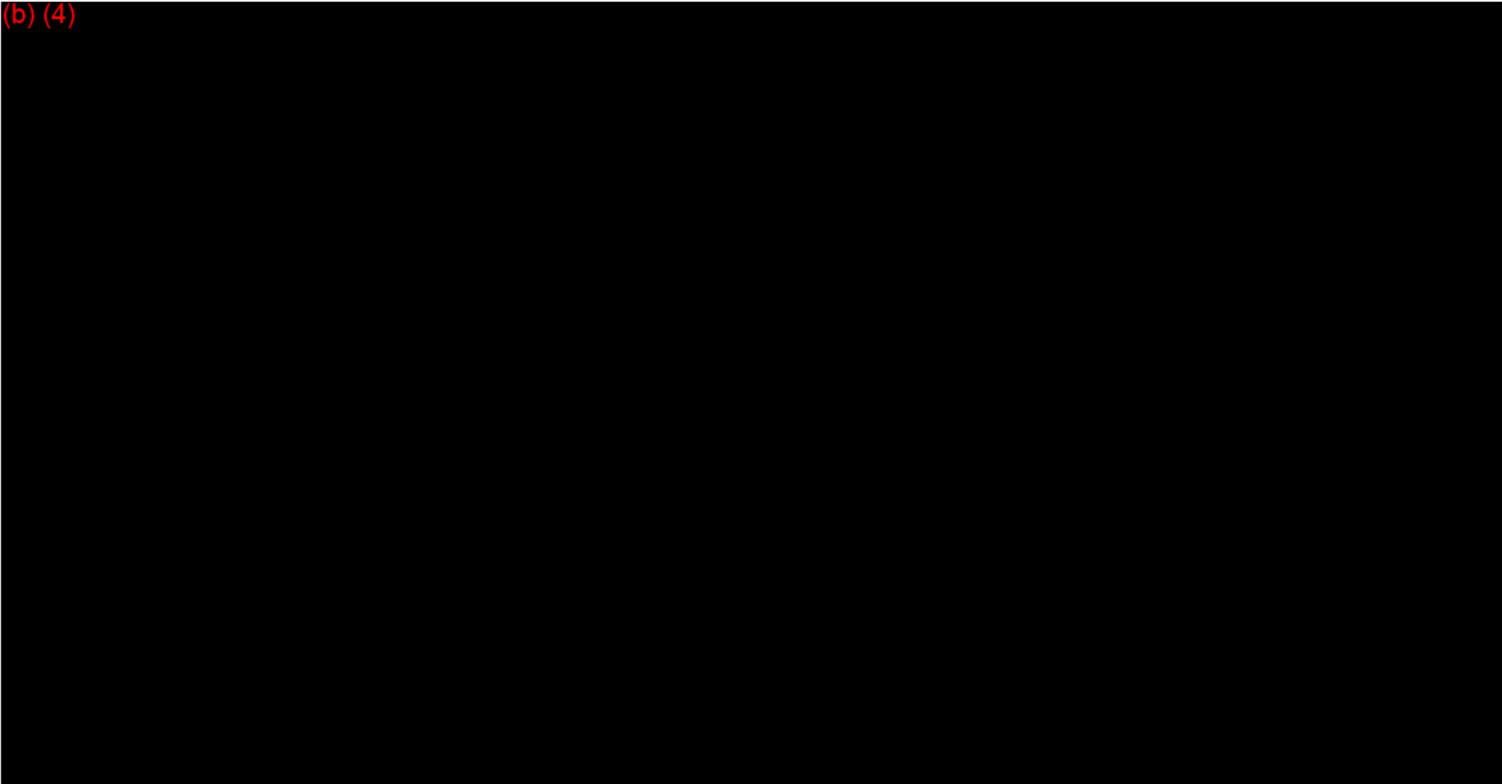
From: Lim, Lisa
To: dustyn@cytoplast.com
Sent: Tuesday, September 25, 2007 3:57 PM
Subject: [SPAM] K072076

Dustin,

(b) (4)



(b) (4)



Thanks,

Lisa M. Lim, Ph.D.

Biomedical Engineer

Food & Drug Administration

Plastic & Reconstructive Surgery Devices Branch

9200 Corporate Blvd., HFZ-410

Rockville, MD 20850

(240) 276-3555 *New*

fax: (240) 276-3733 *New*

Lisa.Lim@fda.hhs.gov

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone.

9/28/2007

258

Lim, Lisa

From: Dustyn Webb [dustyn@cytoplast.com]
Sent: Tuesday, September 25, 2007 6:17 PM
To: Lim, Lisa
Subject: Re: K072076
Attachments: Osteogenics - 4 year AA suture validation.pdf

Lisa,

See attached 4-year accelerated aging study for our Cytoplast PTFE Suture.

Best Regards,

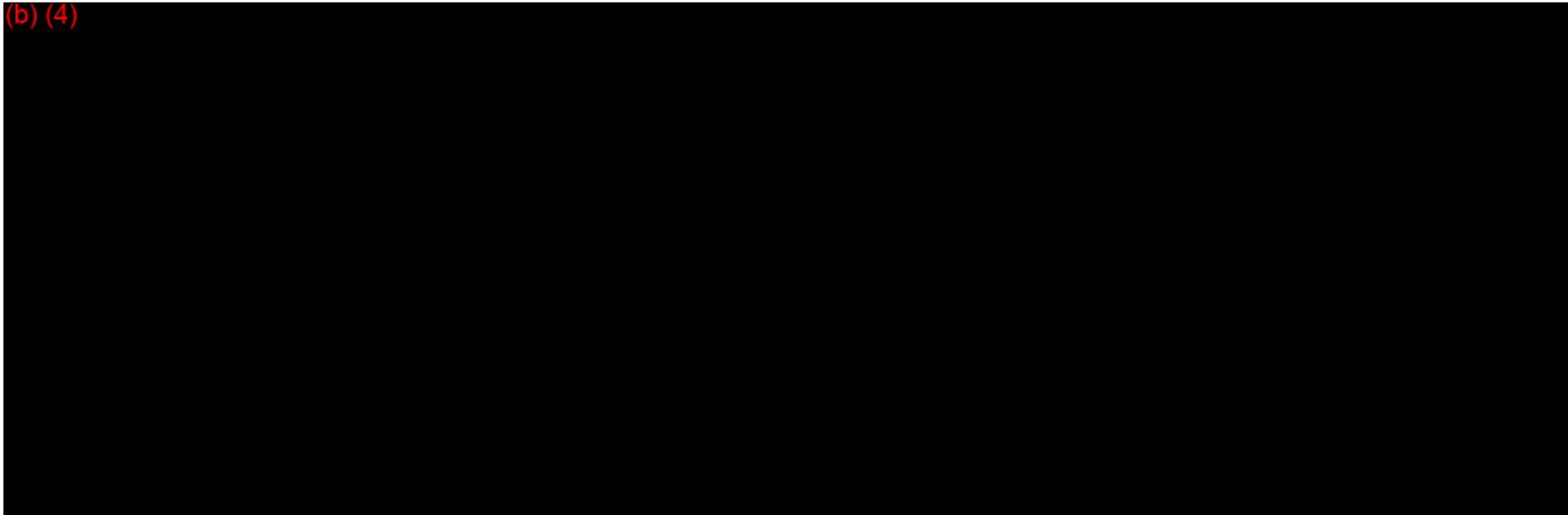
Dustyn Webb
Osteogenics Biomedical, Inc.
(806) 796-1923
dustyn@cytoplast.com

Lim, Lisa

From: Lim, Lisa
Sent: Tuesday, September 25, 2007 4:58 PM
To: 'dustyn@cytoplast.com'
Subject: K072076

Dustin,

(b) (4)



Thanks,

Lisa M. Lim, Ph.D.
Biomedical Engineer
Food & Drug Administration
Plastic & Reconstructive Surgery Devices Branch
9200 Corporate Blvd., HFZ-410
Rockville, MD 20850
(240) 276-3555 *New*
fax: (240) 276-3733 *New*
Lisa.Lim@fda.hhs.gov

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October 11, 2007

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-40)
9200 Corporate Blvd.
Rockville, Maryland 20850

OSTEOGENICS BIOMEDICAL, INC.
4620 71ST ST., BLDG. 78-79
LUBBOCK, TX 79424
ATTN: DUSTYN WEBB

510(k) Number: K072076
Product: CYTOPLAST PTFE
SUTURE

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (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. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1567.html>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 28 2007

Osteogenics Biomedical, Inc.
% Mr. Dustyn Webb
Regulatory/Quality Manager
4620 71st Street, Building 78-79
Lubbock, Texas 79424

Re: K072076
Trade Name: Cytoplast PTFE Suture
Dated: July 25, 2007
Received: July 30, 2007

FDA CDRH DMC

OCT 09 2007

Received

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following information.

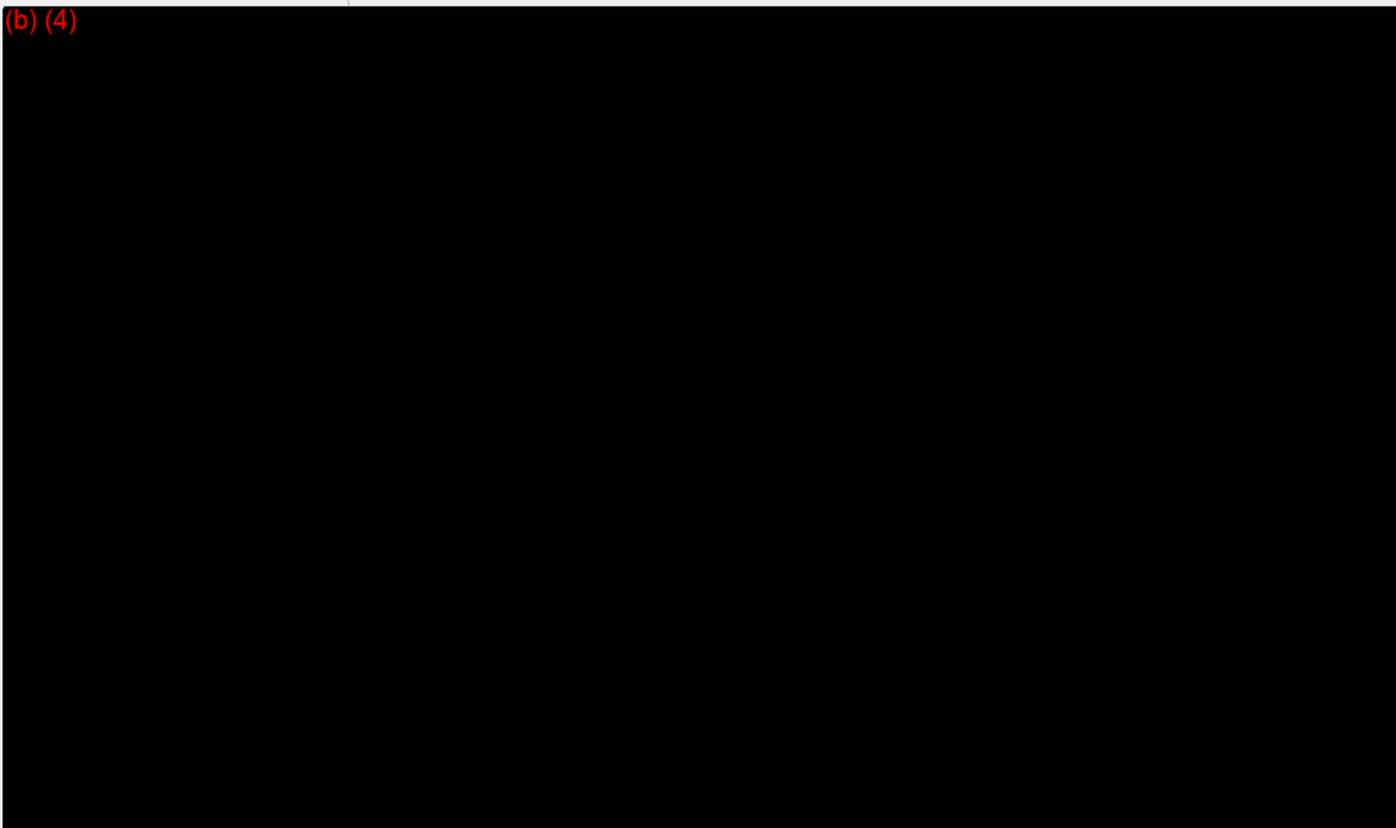
(b) (4)



Handwritten mark resembling a stylized '2' or '7'.

Page 2 – Mr. Dustyn Webb

(b) (4)



The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(j) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device.

We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. Please note our guidance document entitled, "Guidance for Industry and

Page 3 – Mr. Dustyn Webb

FDA Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

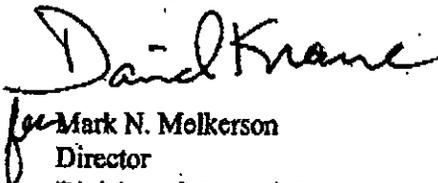
The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/cdrh/ndufma/guidance/1219.html>.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning the contents of the letter, please contact Lisa M. Lim, Ph.D. at (240) 276-3555. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (240) 276-3150, or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



for Mark N. Molkerson
Director
Division of General, Restorative
and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

(1) Indications for Use Form ODE Revised.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 28 2007

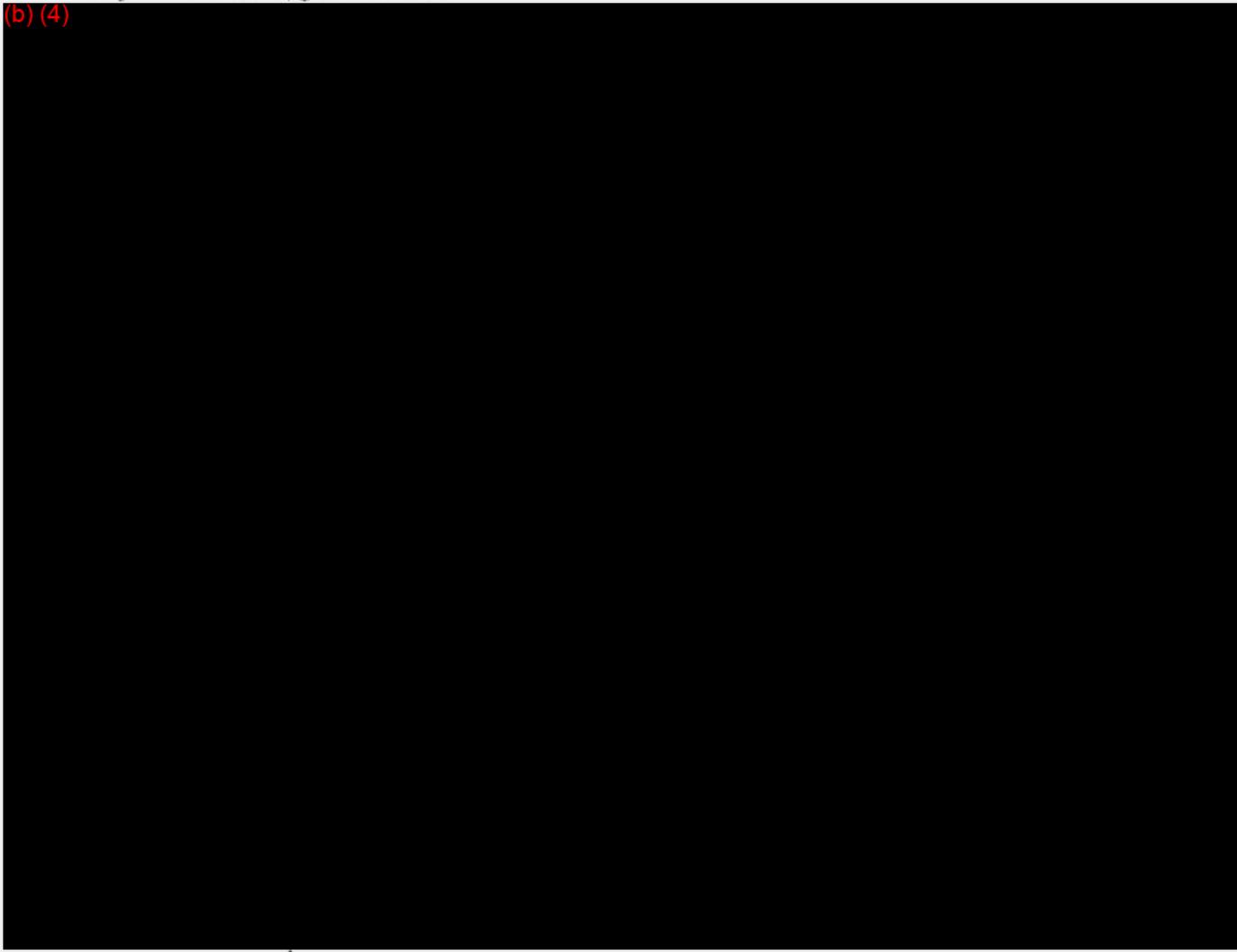
Osteogenics Biomedical, Inc.
% Mr. Dustyn Webb
Regulatory/Quality Manager
4620 71st Street, Building 78-79
Lubbock, Texas 79424

Re: K072076
Trade Name: Cytoplast PTFE Suture
Dated: July 25, 2007
Received: July 30, 2007

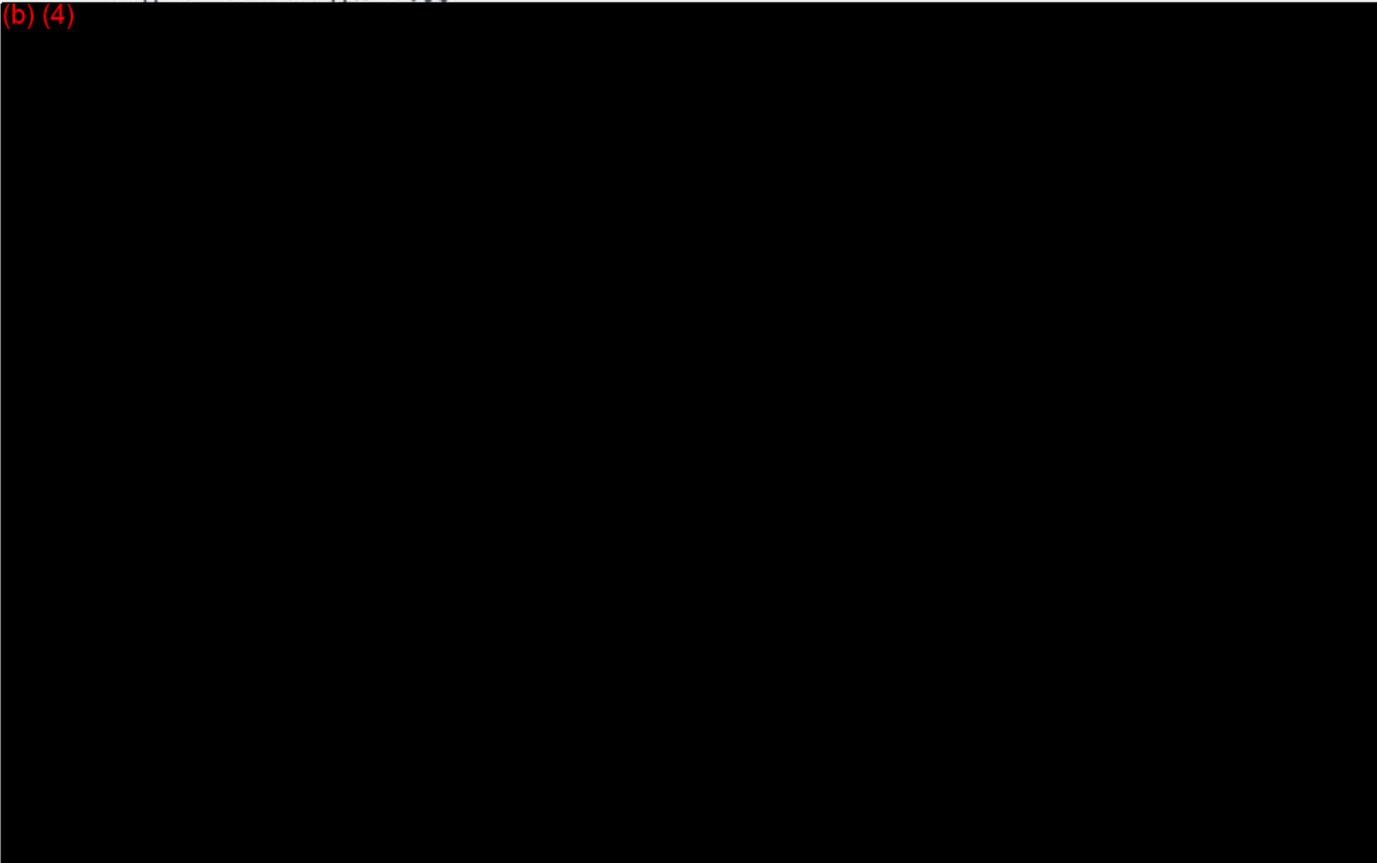
Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following information.

(b) (4)



(b) (4)



The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device.

We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

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Page 3 – Mr. Dustyn Webb

FDA Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

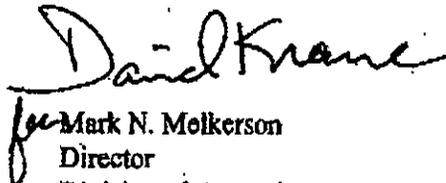
The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning the contents of the letter, please contact Lisa M. Lim, Ph.D. at (240) 276-3555. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (240) 276-3150, or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



for Mark N. Molkerson
Director
Division of General, Restorative
and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

(1) Indications for Use Form ODE Revised.

K072076/S1

1	Cytoplast PTFE Suture USP Requirements Data
2	Cytoplast PTFE Suture 4-Year Shelf Life Data
3	Cytoplast PTFE Suture Ethylene Oxide (EO) Residuals Data
4	Cytoplast PTFE Suture LAL Endotoxin Testing Data
5	Cytoplast PTFE Suture Marketed Sizes
6	Cytoplast PTFE Suture Truthful & Accuracy Statement
7	Cytoplast PTFE Suture 510(k) Statement
8	Cytoplast PTFE Suture Indications For Use Page

1	Cytoplast PTFE Suture USP Requirements Data
2	Cytoplast PTFE Suture 4-Year Shelf Life Data
3	Cytoplast PTFE Suture Ethylene Oxide (EO) Residuals Data
4	Cytoplast PTFE Suture LAL Endotoxin Testing Data
5	Cytoplast PTFE Suture Marketed Sizes
6	Cytoplast PTFE Suture Truthful & Accuracy Statement
7	Cytoplast PTFE Suture 510(k) Statement
8	Cytoplast PTFE Suture Indications For Use Page

Cytoplast Suture REF	Cytoplast Diameter (mm)	USP Size	Diameter Limits (mm)	Cytoplast Knot-Pull Average (kgf)	USP Knot-Pull Average (kgf)	Cytoplast Knot-Pull Individual Minimum (kgf)	USP Knot-Pull Individual Minimum (kgf)	Cytoplast Needle Attachment Average (kgf)	USP Needle Attachment Average (kgf)	Cytoplast Needle Attachment Individual Minimum (kgf)	USP Needle Attachment Individual Minimum (kgf)
CS0618RC CS0618PREM CS0618PERIO	(b) (4)	4-0	0.15- 0.199	(b) (4)	0.46	(b) (4)	-	(b) (4)	0.45	(b) (4)	0.23
				(b) (4)	0.66	(b) (4)	-	(b) (4)	0.34		
				(b) (4)	1.02	(b) (4)	-	(b) (4)	0.45		
CS0518		3-0	0.20- 0.249								
CS0418		2-0	0.30- 0.349								

USP Table

Cytoplast Suture REF	Cytoplast Diameter (mm)	USP Size	Diameter Limits (mm)	Cytoplast Knot-Pull Average (kgf)	USP Knot-Pull Average (kgf)	Cytoplast Knot-Pull Individual Minimum (kgf)	USP Knot-Pull Individual Minimum (kgf)	Cytoplast Needle Attachment Average (kgf)	USP Needle Attachment Average (kgf)	Cytoplast Needle Attachment Individual Minimum (kgf)	USP Needle Attachment Individual Minimum (kgf)
CS0618RC CS0618PREM CS0618PERIO	(b) (4)	4-0	0.15- 0.199	(b) (4)	0.46	(b) (4)	-	(b) (4)	0.45	(b) (4)	0.23
CS0518		3-0	0.20- 0.249		0.66		-		0.68		0.34
CS0418		2-0	0.30- 0.349		1.02		-		1.10		0.45

USP Table

Cytoplast Suture REF	USP Size	Diameter Limits (mm)	Time 0 Cytoplast Knot-Pull Average (kgf)	4-Year AA Cytoplast Knot-Pull Average (kgf)	Time 0 Cytoplast Needle Attachment Average (kgf)	4-Year AA Cytoplast Needle Attachment Average (kgf)
CS0618RC CS0618PREM CS0618PERIO	4-0	0.15- 0.199				
CS0518	3-0	0.20- 0.249				
CS0418	2-0	0.30- 0.349				

(b) (4)

4-Year Shelf Life Table

Cytoplast Suture REF	USP Size	Diameter Limits (mm)	Time 0 Cytoplast Knot-Pull Average (kgf)	4-Year AA Cytoplast Knot-Pull Average (kgf)	Time 0 Cytoplast Needle Attachment Average (kgf)	4-Year AA Cytoplast Needle Attachment Average (kgf)
CS0618RC CS0618PREM CS0618PERIO	4-0	0.15- 0.199				
CS0518	3-0	0.20- 0.249				
CS0418	2-0	0.30- 0.349				

(b) (4)

4-Year Shelf Life Table

DETERMINATION OF ETHYLENE OXIDE RESIDUALS

Osteogenics has accepted as its standards for EO residuals the proposed limit values published by ANSI/AAMI/ISO 10993-7:1995.

Residue Limit Values (mg) Per 24 Hours

<u>Residue</u>	<u>mg/24 Hours</u>
Ethylene Oxide	< 20 mg
Ethylene Chorohydrin	< 12 mg

It was validated that excessive EO residuals would not be present on the Cytoplast® PTFE Suture after the sterilization cycle.

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

From: "Christy Turner" <Christy.turner@apptec-usa.com>

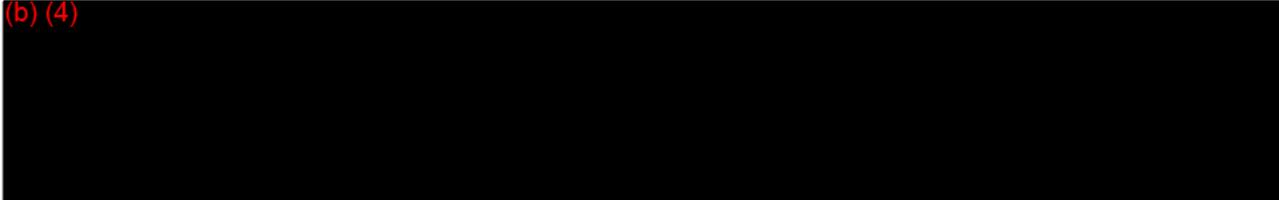
To: "Dustyn Webb" <dustyn@cytoplast.com>

Sent: Friday, October 05, 2007 6:43 AM

Subject: [SPAM] RE: Endotoxin Samples: Cytoplast PTFE Suture

Good Morning Dustyn,

(b) (4)



Thank you,

Christy Turner

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

From: "Christy Turner" <Christy.turner@apptec-usa.com>

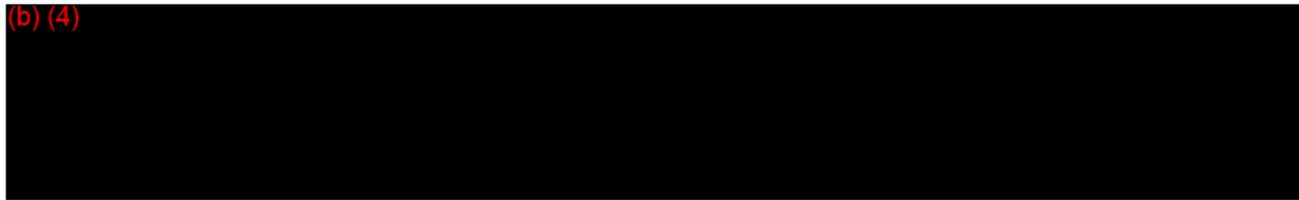
To: "Dustyn Webb" <dustyn@cytoplast.com>

Sent: Friday, October 05, 2007 6:43 AM

Subject: [SPAM] RE: Endotoxin Samples: Cytoplast PTFE Suture

Good Morning Dustyn,

(b) (4)



Thank you,

Christy Turner

OSTEOGENICS

B I O M E D I C A L

Cytoplast® PTFE Suture

Endotoxin testing (LAL): Quarterly schedule



CYTOPLAST

4620 71st Street, Bldg 78 • Lubbock, TX 79424
phone 888.796.1923 • fax 806.796.0059
osteogenics@cytoplast.com • www.cytoplast.com

PermaRidge
Alveolar Ridge Hydroxylapatite Matrix

Cytoplast® PTFE Suture

Endotoxin testing (LAL): Quarterly schedule



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PermaRidge
Alveolar Ridge Hydroxylapatite Matrix

**Cytoplast[®]
PTFE Suture
Sizes**

USP 2-0

USP 3-0

USP 4-0

**Cytoplast[®]
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USP 2-0

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USP 4-0

OSTEOGENICS

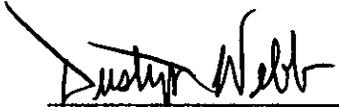
B I O M E D I C A L

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURACY STATEMENT

(AS REQUIRED BY 21 CFR 807.87 (k))

I certify that, in my capacity as *Regulatory/Quality Manager of Osteogenics Biomedical, Inc.*, I believe, to the best of my knowledge, that all data and information submitted in the Abbreviated 510(k) Premarket Notification are truthful and accurate, and that no material fact has been omitted.



Dustyn Webb
Regulatory/Quality Manager
Osteogenics Biomedical, Inc.

04 Oct 2007
Date


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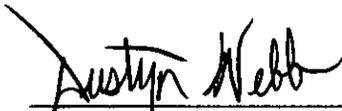
PermaRidge[®]
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Dustyn Webb
Regulatory/Quality Manager
Osteogenics Biomedical, Inc.

04 Oct 2007

Date

OSTEOGENICS

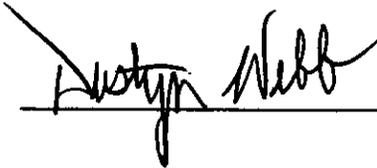
B I O M E D I C A L

PREMARKET NOTIFICATION

510(k) STATEMENT

(As Required By 21 CFR 807.93)

I certify that, in my capacity as **Regulatory/Quality Manager of Osteogenics Biomedical, Inc.**, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.



Dustyn Webb

04 October 2007

Premarket Notification [510(k)] Number – K072076


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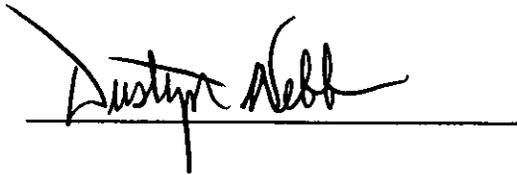
B I O M E D I C A L

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Dustyn Webb

04 October 2007

Premarket Notification [510(k)] Number – K072076


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PermaRidge[®]
Alveolar Ridge Hydroxylapatite Matrix

Indications for Use

510(k) Number (if known): K072076

Device Name: Cytoplast PTFE Suture

Indications For Use:

The Cytoplast[®] PTFE Suture is indicated for use in all types of soft tissue approximation and/or ligation, including cardiovascular, dental and general surgeries, as well as repair of the dura mater. The device is not indicated for use in ophthalmic surgery, microsurgery and peripheral neural tissue.

Prescription Use
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)