



# U.S. Department of Health & Human Services

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**Food and Drug Administration**

## SAVE REQUEST

**USER:** (kml)

**FOLDER:** K003028 - 77 pages

**COMPANY:** OSTEOGENICS BIOMEDICAL, INC. (OSTEBIOMA)

**PRODUCT:** SUTURE, SURGICAL, NONABSORBABLE, EXPANDED, POLYTETRAFLUROETHYLENE (NBY)

**SUMMARY:** Product: CYTOPLAST SUTURE; CS-0318, CS-0416, CS-0418, CS-0513, CS-0513PC, CS-05

**DATE REQUESTED:** Nov 4, 2015

**DATE PRINTED:** Nov 4, 2015

**Note:** Printed



NOV 24 2000

K003028

510 (k) SUMMARY

**I. ADMINISTRATIVE**

Submitter: Osteogenics Biomedical, Inc.  
3234 64th Street  
Lubbock, TX 79413  
(806) 792-2311

Contact Person: Chad Bartee

Date of Preparation: November 8, 2000

**II. DEVICE NAME**

Proprietary Name: Cytoplast™ Suture

Common Name: Non-Absorbable m-PTFE Surgical Sutures

Classification Name: Suture, Nonabsorbable, Synthetic, Polytetrafluorethylene

**III. PREDICATE DEVICE**

Gore-Tex™ e-PTFE Sutures; W.L Gore & Associates, Inc.

**IV. DEVICE DESCRIPTION**

The Cytoplast™ Suture is a nonabsorbable, sterile surgical monofilament suture composed of polytetrafluoroethylene that has been expanded to produce a microporous structure (m-PTFE). The Cytoplast™ Suture meets all requirements in the USP 24 monograph for Nonabsorbable Surgical Sutures. The suture is undyed and contains no additives. The Cytoplast™ Suture is supplied sterile with attached standard surgical needles in a variety of sizes.

**V. INTENDED USE**

The Cytoplast™ Suture is intended for use in the approximation and ligation of soft tissue in the oral cavity, including fixation of barrier membranes. The intended use of the predicate device, Gore-Tex™ e-PTFE Sutures, is broader, including cardiovascular surgery and dura mater repair. However, Osteogenics Biomedical has limited the intended use to the dental surgical market in which it operates.

## VI. COMPARISON TO PREDICATE DEVICE

	Cytoplast™ m-PTFE Suture	Predicate Device
Intended Use:	Approximation and ligation of soft tissue in the oral cavity, including fixation of barrier membranes.	Soft tissue approximation and/or ligation, including use in cardiovascular surgery and dura mater repair.
Suture material:	Polytetrafluoroethylene (100%); expanded	Polytetrafluoroethylene (100%); expanded
Suture Characteristics:	Not absorbed and no significant changes known to occur <i>in vivo</i> .	Not absorbed and no significant changes known to occur <i>in vivo</i> .
How Supplied:	Sterile monofilament thread, undyed, 24-inches long in various sizes with attached needles.	Sterile monofilament thread, undyed, 24-inches long in various sizes with attached needles.
Use (single, reusable, disposable)	Single Use Only.	Single use Only.
Suture Diameter Suture Length Needle Attachment Strength Knot Pull Tensile Strength	Meets U.S.P. requirements.	Differs from U.S.P. requirements in diameter and knot-pull tensile strength.
Packaging	Dry packaged in paper/polyester-polypropylene tear-open pouch.	Same or equivalent manner.

Based on this comparison, Osteogenics Biomedical, Inc. concludes that the Cytoplast™ Suture is safe and effective for its intended use and performs at least as well as the predicate device.



NOV 24 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Osteogenics Biomedical, Inc.  
c/o Mr. Richard A. Hamer  
Richard Hamer Associates, Inc.  
6401 Meadows West Drive  
Fort Worth, Texas 76132

Re: K003028  
Trade Name: Osteogenics Biomedical, Inc. Cytoplast™ Sutures  
Regulatory Class: II  
Product Code: NBY  
Dated: September 27, 2000  
Received: September 28, 2000

Dear Mr. Bartee:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

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

Page 2 - Mr. Chaddick M. Bartee

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

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

Sincerely yours,

*for Mark A. Milburn*

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**K003028**

Page 1 of 1

510(k) Number (if known): \_\_\_\_\_

Device Name: Cytoplast™ Sutures

**Indications for Use:**

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

(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 \_\_\_\_\_

(Optional Format 1-2-96)

*for Mark N. Milkunas*

(Division Sign-Off)  
Division of General Restorative Devices

510(k) Number \_\_\_\_\_

**K003028**



NOV 24 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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c/o Mr. Richard A. Hamer  
Richard Hamer Associates, Inc.  
6401 Meadows West Drive  
Fort Worth, Texas 76132

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Regulatory Class: II  
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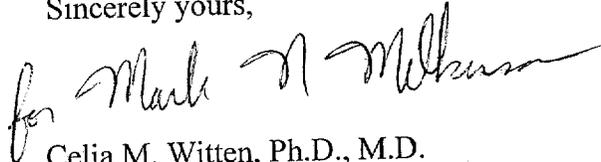
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Sincerely yours,

*for* 

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
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Page 1 of 1

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(Optional Format 1-2-96)

for Mark N. Milkus  
(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K003028

Memorandum

From: Reviewer(s) - Name(s) *C. M. ...*

Subject: 510(k) Number 15 06 3028

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.

*K-1 SE*

De Novo Classification Candidate?  YES  NO

Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Postmarket Surveillance?  YES  NO
- Is this device subject to the Tracking Regulation?  YES  NO
- Was clinical data necessary to support the review of this 510(k)?  YES  NO
- Is this a prescription device?  YES  NO
- Was this 510(k) reviewed by a Third Party?  YES  NO
- Special 510(k)?  YES  NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers  YES  NO

This 510(k) contains:

- Truthful and Accurate Statement  Requested  Enclosed  
(required for originals received 3-14-95 and after)
- A 510(k) summary OR  A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form (required for originals received 1-1-96 and after)
- Material of Biological Origin  YES  NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Predicate Product Code with class: \_\_\_\_\_ Additional Product Code(s) with panel (optional): \_\_\_\_\_

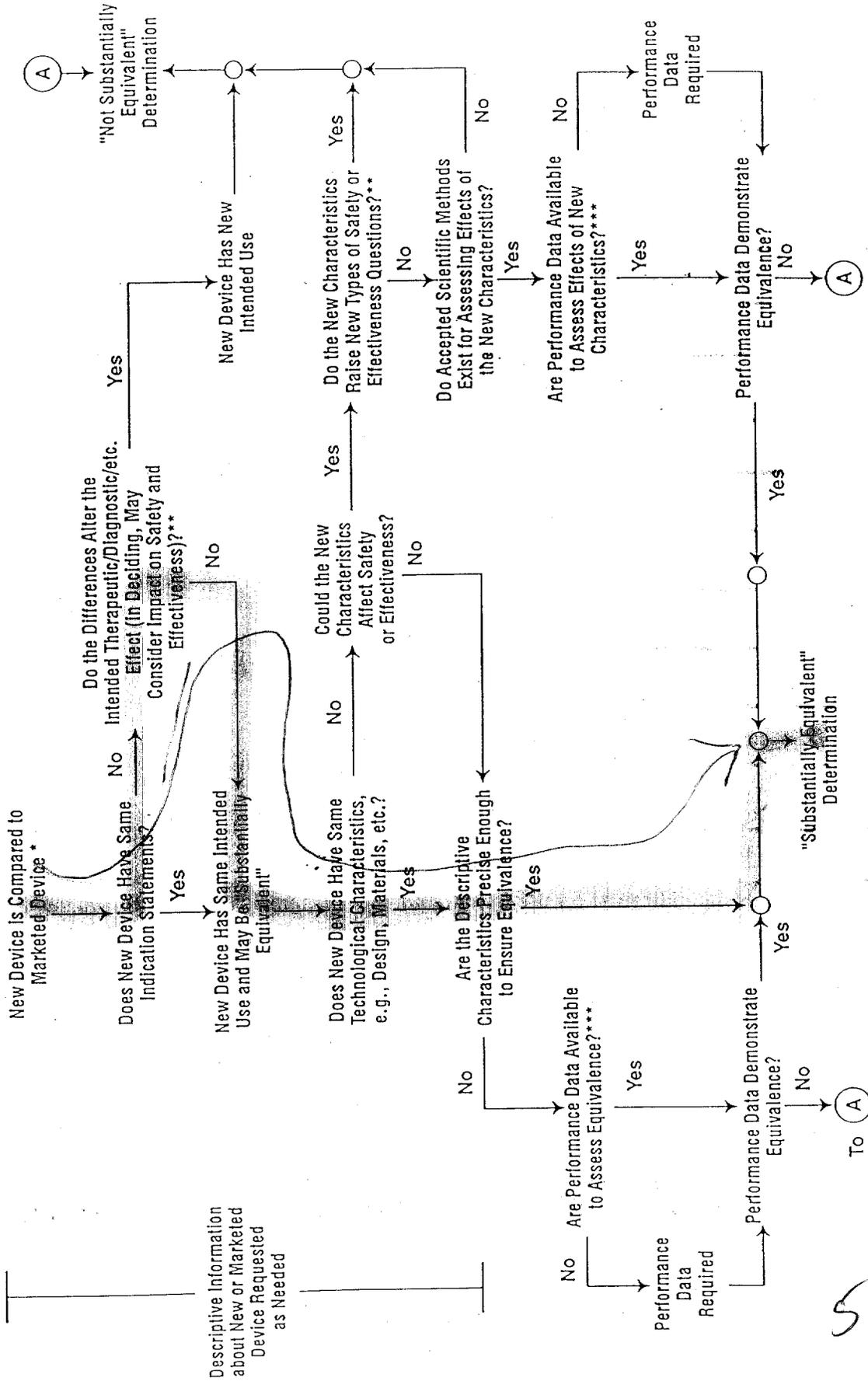
*79 Nonabsorbable & PTFE surgical sutures*

*NBY Class II*

Review: *Steph Rloods* *PK 511* *11/16/00*  
(Branch Chief) (Branch Code) (Date)

Final Review: *Mark N. Melhorn* *11/29/00*  
(Division Director) (Date)

# 510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



\* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information if the Relationship Between Marketed and "Predicate" (Pre-Amended) or Reclassified Post-Amendments) Devices is Unclear.  
 \*\* This Decision is Normally Based on Descriptive Information Alone, But Limited Testing Information is Sometimes Required.  
 \*\*\* Data in the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

# Screening Checklist

## For all Premarket Notification 510(k) Submissions

Device Name: <i>Cytoplast Suture</i>		K 003028					
Submitter (Company): <i>Osteogenics Biomedical</i>							
Items which should be included <i>(circle missing &amp; needed information)</i>	S P E C I A L	A B B R E V I A T E D	T R A D I T I O N A L	✓ IF ITEM IS NEEDED AND IS MISSING			
	YES	NO	YES		NO	YES	NO
1. Cover Letter clearly identifies Submission as:							
a) "Special 510(k): Device Modification"				X			
b) "Abbreviated 510(k)"							
c) Traditional 510(k)							
		GO TO # 2,3		GO TO # 2,4,5		GO TO #2, 5	
2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS				✓ IF ITEM IS NEEDED			
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)		NA		YES		NO	
		SPECIALS		ABBREVIATED		TRADITIONAL	
		YES	NO	YES	NO	YES	NO
		AND IS MISSING					
a) trade name, classification name, establishment registration number, device class						✓	
b) OR a statement that the device is not yet classified		FDA-may be a classification request; see coordinator					
c) identification of legally marketed equivalent device		NA					
d) compliance with Section 514 - performance standards		NA					
e) address of manufacturer							
f) Truthful and Accurate Statement							
g) Indications for Use enclosure							
h) SMDA Summary or Statement (FOR ALL DEVICE CLASSES)							
i) Class III Certification & Summary (FOR ALL CLASS III DEVICES)							
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals							
k) Proposed Labeling:							
i) package labeling (user info)							
ii) statement of intended use							
iii) advertisements or promotional materials							
i) MRI compatibility (if claimed)							
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:							
i) Labeling							
ii) intended use							
iii) physical characteristics							
iv) anatomical sites of use							
v) performance (bench, animal, clinical) testing		NA					
vi) safety characteristics		NA					
m) If kit, kit certification							
3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE							
a) Name & 510(k) number of legally marketed (unmodified) predicate device							6
b) STATEMENT - INTENDED USE AND INDICATIONS FOR				* If no - STOP not a special			

<b>USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED*</b>				
c) <b>STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED*</b>				* If no - STOP not a special
d) Design Control Activities Summary				
i) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis				
ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied				
iii) A declaration of conformity with design controls. The declaration of conformity should include:				
1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met				
2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure Requirements as specified in 21 CFR 820.30 and the records are available for review.				

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
<b>4. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS - PLEASE FILL OUT THE STANDARDS ABBREVIATED FORM ON THE H DRIVE</b>							
a) For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type							
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:							
i) An identification of the applicable recognized consensus standards that were met							
ii) A specification, for each consensus standard, that all requirements were met, except for							7

inapplicable requirements or deviations noted below		
iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed		
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device		
v) A specification of any deviations from each applicable standard that were applied		
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference		
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations		
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards		

5. Additional Considerations: (may be covered by Design Controls)							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:							
i) component & material							
ii) identify patient-contacting materials							
iii) biocompatibility of final sterilized product							
b) Sterilization and expiration dating information:							
i) sterilization method							
ii) SAL							
iii) packaging							
iv) specify pyrogen free							
v) ETO residues							
vi) radiation dose							
c) Software validation & verification:							
i) hazard analysis							
ii) level of concern							
iii) development documentation							
iv) certification							

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening  Yes  No  
Date: \_\_\_\_\_

Reviewer: \_\_\_\_\_  
Concurrence by Review Branch: \_\_\_\_\_

8

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

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

Reviewer: *W. Huda* <sup>K</sup> 003028  
 Division/Branch: *DEPT OF HEALTH*  
 Device Name: *Cytoplast Salines*  
 Product To Which Compared (510(K) Number If Known): *Gen-Tek Salines*

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

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

*See memo*

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

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

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

## Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		
2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes?		
4. If, not, has POS been notified?		
5. Is the product a device?		
6. Is the device exempt from 510(k) by regulation or policy?		
7. Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE decision?		
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

**MEMO TO THE RECORD  
510(K) REVIEW  
K003028**

DATE: 11/9/00  
OFFICE: HFZ-410  
DIVISION: DGRD/PRSB  
FROM: Biologist  
DEVICE NAME: Cytoplast Suture: CS-0318, CS-0416, CS-0418, CS-0513, CS-0516HC,  
CS-0513PC  
COMPANY NAME: Osteogenics Biomedical, Inc.  
CONTACT: (b) (6)  
PHONE: [REDACTED]

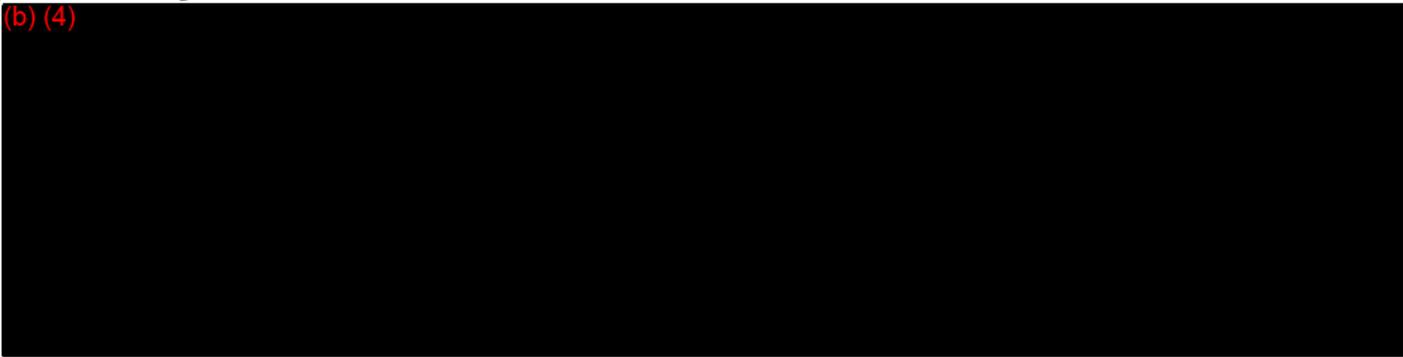
NARRATIVE DEVICE DESCRIPTION

INTENDED USE:

Indications for Use: A removable, nonabsorbable suture for approximation and ligation of soft tissue in the oral cavity, including fixation of barrier membranes.

Predicate Indications for Use: Soft tissue approximation and/or ligation, including use in cardiovascular surgery and dura mater repair. These indications are identical to the indications for use specified in the ePTFE suture guidance document.

(b) (4)



DEVICE DESCRIPTION:

Is the device:

- |                                          |                  |
|------------------------------------------|------------------|
| 1. Life-supporting or life-sustaining?   | No.              |
| 2. Implant (short-term or long-term)?    | Yes, short term. |
| 3. Software-driven?                      | No.              |
| 4. Sterile?                              | Yes.             |
| 5. Single use?                           | Yes.             |
| 6. For home or prescription use?         | Prescription.    |
| 7. Contain a drug or biologic component? | No.              |
| 8. A kit?                                | No.              |

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

SUMMARY

The Cytoplast Suture is a non-absorbable, sterile surgical monofilament suture composed of polytetrafluoroethylene that has been expanded to produce a nanoporous microstructure (n-PTFE). The suture is undyed and contains no additives. It is supplied with attached standard surgical needles in a variety of sizes.

(b)(4)

MATERIALS:

(b)(4)

STERILITY:

(b)(4)

PACKAGING: Dry packaged in paper/polyester-polypropylene tear-open pouch

LABELING:

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

SAFETY AND EFFECTIVENESS INFORMATION: The sponsor has provided a summary of safety and effectiveness.

RECOMMENDATION: Substantially equivalent to 79 (NBY) Non-absorbable ePTFE surgical suture.

CLASSIFICATION: Class II

 11/9/00

Peter L. Hudson, Ph.D.

Reviewer

Division of General and Restorative Devices

Plastic and Reconstructive Surgery Branch



RICHARD HAMER ASSOCIATES, INC.  
REGULATORY CONSULTANTS

# FAX

## CONFIDENTIALITY NOTICE

This facsimile transmission (and/or the documents accompanying it) is privileged and confidential information intended only for the use of the individual or entity named below. If the reader of this message is not the intended recipient, or the employee or agent responsible to deliver it to the intended recipient, you are hereby notified that any disclosure, copying, distribution, or the taking of any action in reliance on the contents of this communication is strictly prohibited. If you have received this communication in error, please immediately notify us by telephone and return the original message to us by mail at the address below.

DATE: November 9, 2000  
TO: Dr. Peter Hudson  
FDA/CDRH/ODE  
FROM: Richard A. Hamer  
PAGES: 5

Dear Dr. Hudson:

Further to our telephone conversation, attached are revised 510(k) summary (pages 10-11), pouch label (page 13) and first package insert page (page 14) for the Cytoplast™

(b)(4)

Duplicate copies of these pages are being forwarded today via first class mail. Should you have any questions or require additional information, please do not hesitate to contact me.

Sincerely,

Richard A. Hamer  
Consultant to Osteogenics Biomedical, Inc.

cc: Mr. Chad Bartee, Osteogenics Biomedical, Inc.

RAH/mlm

(817) 294-3644 • FAX (817) 294-3761 • Email: rhamer@hamerassoc.com

Offices: 6401 Meadows West Dr., Fort Worth, TX 76132  
Mailing Address: P.O. Box 16598, Fort Worth, TX 76162-0598

15

Pouch Label

STERILE  
FOR SINGLE USE ONLY

LOT:

**Cytoplast™ Suture**  
**m-PTFE Nonabsorbable Monofilament Suture, U.S.P.**

(Model #, Dimensions)

See Instructions for Use

Osteogenics Biomedical, Inc.  
Lubbock, Texas 79413

Package Insert

**Cytoplast™ Sutures**  
**m-PTFE Nonabsorbable Monofilament Suture, U.S.P**

**Description**

The Cytoplast™ Suture is a nonabsorbable, monofilament suture manufactured from polytetrafluoroethylene that has been expanded to produce a microporous structure (m-PTFE). The microporous nature of the m-PTFE enables it to be swaged to needles that closely approximate the diameter of the thread, without compromising the strength of the needle attachment. The suture is undyed and contains no additives. The Cytoplast™ Suture meets all USP requirements.

**Actions**

PTFE has been shown in clinical trials to elicit minimal tissue reaction. The Cytoplast™ Suture is not absorbed or subject to weakening by the action of tissue enzymes.

The internodal spaces of m-PTFE permit infiltration of fibroblasts and leukocytes. Tissue attaches to and collagen penetrates into the Cytoplast™ Suture.

**Indications**

The Cytoplast™ Suture is indicated for use in approximation and ligation of soft tissue in the oral cavity, including fixation of barrier membranes.

**Contraindications**

This device is contraindicated for use in ophthalmic surgery, microsurgery, and peripheral neural tissue.

**Warnings**

Tissue invasion of the m-PTFE suture can result in attachment of the suture to the tissue it penetrates. Such attachment may make removal of the suture difficult.

## 510 (k) SUMMARY

### I. ADMINISTRATIVE

**Submitter:** Osteogenics Biomedical, Inc.  
3234 64th Street  
Lubbock, TX 79413  
(806) 792-2311

**Contact Person:** Chad Bartee

**Date of Preparation:** November 8, 2000

### II. DEVICE NAME

**Proprietary Name:** Cytoplast™ Suture

**Common Name:** Non-Absorbable m-PTFE Surgical Sutures

**Classification Name:** Suture, Nonabsorbable, Synthetic, Polytetrafluorethylene

### III. PREDICATE DEVICE

Gore-Tex™ e-PTFE Sutures; W.L Gore & Associates, Inc.

### IV. DEVICE DESCRIPTION

The Cytoplast™ Suture is a nonabsorbable, sterile surgical monofilament suture composed of polytetrafluoroethylene that has been expanded to produce a microporous structure (m-PTFE). The Cytoplast™ Suture meets all requirements in the USP 24 monograph for Nonabsorbable Surgical Sutures. The suture is undyed and contains no additives. The Cytoplast™ Suture is supplied sterile with attached standard surgical needles in a variety of sizes.

### V. INTENDED USE

The Cytoplast™ Suture is intended for use in the approximation and ligation of soft tissue in the oral cavity, including fixation of barrier membranes. The intended use of the predicate device, Gore-Tex™ e-PTFE Sutures, is broader, including cardiovascular surgery and dura mater repair. However, Osteogenics Biomedical has limited the intended use to the dental surgical market in which it operates.

## VI. COMPARISON TO PREDICATE DEVICE

	Cytoplast™ m-PTFE Suture	Predicate Device
Intended Use:	Approximation and ligation of soft tissue in the oral cavity, including fixation of barrier membranes.	Soft tissue approximation and/or ligation, including use in cardiovascular surgery and dura mater repair.
Suture material:	Polytetrafluoroethylene (100%); expanded	Polytetrafluoroethylene (100%); expanded
Suture Characteristics:	Not absorbed and no significant changes known to occur <i>in vivo</i> .	Not absorbed and no significant changes known to occur <i>in vivo</i> .
How Supplied:	Sterile monofilament thread, undyed, 24-inches long in various sizes with attached needles.	Sterile monofilament thread, undyed, 24-inches long in various sizes with attached needles.
Use (single, reusable, disposable)	Single Use Only.	Single use Only.
Suture Diameter Suture Length Needle Attachment Strength Knot Pull Tensile Strength	Meets U.S.P. requirements.	Differs from U.S.P. requirements in diameter and knot-pull tensile strength.
Packaging	Dry packaged in paper/polyester-polypropylene tear-open pouch.	Same or equivalent manner.

Based on this comparison, Osteogenics Biomedical, Inc. concludes that the Cytoplast™ Suture is safe and effective for its intended use and performs at least as well as the predicate device.



RICHARD HAMER ASSOCIATES, INC.  
REGULATORY CONSULTANTS

**FAX**

CONFIDENTIALITY NOTICE

This facsimile transmission (and/or the documents accompanying it) is privileged and confidential information intended only for the use of the individual or entity named below. If the reader of this message is not the intended recipient, or the employee or agent responsible to deliver it to the intended recipient, you are hereby notified that any disclosure, copying, distribution, or the taking of any action in reliance on the contents of this communication is strictly prohibited. If you have received this communication in error, please immediately notify us by telephone and return the original message to us by mail at the address below.

DATE: November 8, 2000

TO: Dr. Peter Hudson  
FDA/CDRH/ODE

FROM: Richard A. Hamer

PAGES: 2

Dear Dr. Hudson:

Further to our telephone conversation today, attached is revised "Actions" (b)(4) of the Cytoplast™ Sutures package insert. (b)(4) regarding reduced (b)(4)

(b)(4)

I trust that this revision will permit the issuance of a substantial equivalence determination. Should you have any questions or require additional information, please do not hesitate to contact me.

Sincerely,

Richard A. Hamer  
Consultant to Osteogenics Biomedical, Inc.

cc: Mr. Chad Bartee, Osteogenics Biomedical, Inc.

RAH/mlm

(817) 294-3644 • FAX (817) 294-3761 • Email: rhamer@hamerassoc.com

Offices: 6401 Meadows West Dr., Fort Worth, TX 76132  
Mailing Address: P.O. Box 16598, Fort Worth, TX 76162-0598

Package Insert

**Cytoplast™ Sutures**  
**n-PTFE Nonabsorbable Monofilament Suture, U.S.P**

**Description**

The Cytoplast™ Suture is a nonabsorbable, monofilament suture manufactured from polytetrafluoroethylene that has been expanded to produce a nanoporous microstructure (n-PTFE). The porous nature of the n-PTFE enables it to be swaged to needles that closely approximate the diameter of the thread, without compromising the strength of the needle attachment. The suture is undyed and contains no additives. The Cytoplast™ Suture meets all USP requirements.

**Actions**

PTFE has been shown in clinical trials to elicit minimal tissue reaction. The Cytoplast™ Suture is not absorbed or subject to weakening by the action of tissue enzymes.

The internodal spaces of n-PTFE permit infiltration of fibroblasts and leukocytes. Tissue attaches to and collagen penetrates into the Cytoplast™ Suture.

**Indications**

The Cytoplast™ Suture is indicated for use in approximation and ligation of soft tissue in the oral cavity, including fixation of barrier membranes.

**Contraindications**

This device is contraindicated for use in ophthalmic surgery, microsurgery, and peripheral neural tissue.

**Warnings**

Tissue invasion of the n-PTFE suture can result in attachment of the suture to the tissue it penetrates. Such attachment may make removal of the suture difficult.

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

September 28, 2000

OSTEOGENICS BIOMEDICAL, INC.  
3234 64TH ST.  
LUBBOCK, TX 79413  
ATTN: CHAD BARTEE

510(k) Number: K003028  
Received: 28-SEP-2000  
Product: CYTOPLAST SUTURE;  
CS-0318, CS-0416,  
CS-0418, CS-0513,  
CS-0513PC, CS-0516HC

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

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

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 Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman  
Consumer Safety Officer  
Premarket Notification Staff

20



~~CONFIDENTIAL~~

RICHARD HAMER ASSOCIATES, INC.  
REGULATORY CONSULTANTS

**VIA FEDERAL EXPRESS**

September 27, 2000

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

RECEIVED  
28 SEP 00 11 44  
FDA/CDRH/ODE/DHC

In Re: Cytoplast™ Sutures (Nonabsorbable n-PTFE Surgical Sutures)  
Osteogenics Biomedical, Inc., Lubbock, Texas 79413  
510 (k) Premarket Notification

Gentlemen:

In accordance with the requirements of 21 CFR 807.81, I am pleased to submit herewith, on behalf of Osteogenics Biomedical, Inc., Lubbock, TX, duplicate copies of a 510 (k) notification for the subject device.

Please note that Osteogenics Biomedical, Inc. considers the information provided in this submission to be proprietary and exempt from public disclosure under 21 CFR 20.61.

All data and information contained in this submission was furnished to us by Osteogenics Biomedical, Inc. To the best of our knowledge, it is truthful and accurate, and no material fact has been omitted.

I look forward to your favorable consideration of this premarket notification at your earliest convenience.

Sincerely,

Richard A. Hamer  
Consultant to Osteogenics Biomedical, Inc.

SU  
/H

cc: Mr. Chad Bartee, Osteogenics Biomedical, Inc.

SKIN

23

(817) 294-3644 • Fax (817) 294-3761 • E-mail: rhamer@hamerassoc.com

Offices: 6401 Meadows West Dr., Ft. Worth, TX 76132  
Mailing address: P.O. Box 16598, Ft. Worth, TX 76162-0598

510(k) Premarket Notification

# CYTOPLAST™ Sutures

Nonabsorbable n-PTFE Surgical Sutures

RECEIVED  
28 SEP 00 11 44  
FDA/CDRH/ODE/DHO

Osteogenics Biomedical, Inc.

3234 - 64th Street

Lubbock, Texas 79413

Submission Date: September 27, 2000

24

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**CYTOPLAST™ Sutures**  
**Osteogenics Biomedical, Inc.**

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# CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

## Premarket Submission Cover Sheet

Date of Submission: September 27, 2000

FDA Document Number:

### Section A

### Type of Submission

- |                                                   |                                         |                                        |                                                     |
|---------------------------------------------------|-----------------------------------------|----------------------------------------|-----------------------------------------------------|
| <input checked="" type="checkbox"/> 510(k)        | <input type="checkbox"/> IDE            | <input type="checkbox"/> PMA           | <input type="checkbox"/> PMA Supplement-Regular     |
| <input type="checkbox"/> 510(k) Add'l information | <input type="checkbox"/> IDE Amendment  | <input type="checkbox"/> PMA Amendment | <input type="checkbox"/> PMA Supplement-Special     |
|                                                   | <input type="checkbox"/> IDE Supplement | <input type="checkbox"/> PMA Report    | <input type="checkbox"/> PMA Supplement-30 Day      |
|                                                   | <input type="checkbox"/> IDE Report     |                                        | <input type="checkbox"/> PMA Supplement-Panel Track |

### Section B1

### Reason for Submission - 510(k)s Only

- New Device
- Additional or expanded indications
- Change in technology, design, materials, or manufacturing process
- Other reason (specify):

### Section B2

### Reason for Submission - PMAs Only

- |                                                             |                                                                         |                                              |
|-------------------------------------------------------------|-------------------------------------------------------------------------|----------------------------------------------|
| <input type="checkbox"/> New Device                         | <input type="checkbox"/> Change in design, component, or specification: | <input type="checkbox"/> Location change:    |
| <input type="checkbox"/> Withdrawal                         | <input type="checkbox"/> Software                                       | <input type="checkbox"/> Manufacturer        |
| <input type="checkbox"/> Additional or expanded indications | <input type="checkbox"/> Color Additive                                 | <input type="checkbox"/> Sterilizer          |
| <input type="checkbox"/> Licensing agreement                | <input type="checkbox"/> Other (specify below)                          | <input type="checkbox"/> Packager            |
| <input type="checkbox"/> Labeling change:                   | <input type="checkbox"/> Process change:                                | <input type="checkbox"/> Report submission:  |
| <input type="checkbox"/> Indications                        | <input type="checkbox"/> Manufacturer                                   | <input type="checkbox"/> Annual or periodic  |
| <input type="checkbox"/> Instructions                       | <input type="checkbox"/> Sterilizer                                     | <input type="checkbox"/> Post-approval study |
| <input type="checkbox"/> Performance Characteristics        | <input type="checkbox"/> Packager                                       | <input type="checkbox"/> Adverse reaction    |
| <input type="checkbox"/> Shelf life                         |                                                                         | <input type="checkbox"/> Device defect       |
| <input type="checkbox"/> Trade name                         | <input type="checkbox"/> Response to FDA correspondence (specify below) | <input type="checkbox"/> Amendment           |
| <input type="checkbox"/> Other (specify below)              | <input type="checkbox"/> Request for applicant hold                     |                                              |
| <input type="checkbox"/> Change in ownership                | <input type="checkbox"/> Request for removal of applicant hold          |                                              |
| <input type="checkbox"/> Change in correspondent            | <input type="checkbox"/> Request for extension                          |                                              |
| <input type="checkbox"/> Other reason (specify):            | <input type="checkbox"/> Request to remove or add manufacturing site    |                                              |

### Section B2

### Reason for Submission - IDEs Only

- |                                                        |                                                    |                                                                      |
|--------------------------------------------------------|----------------------------------------------------|----------------------------------------------------------------------|
| <input type="checkbox"/> New Device                    | <input type="checkbox"/> Change in:                | <input type="checkbox"/> Response to FDA letter concerning:          |
| <input type="checkbox"/> Addition of institution       | <input type="checkbox"/> Correspondent             | <input type="checkbox"/> Conditional approval                        |
| <input type="checkbox"/> Expansion/extension of study  | <input type="checkbox"/> Design                    | <input type="checkbox"/> Deemed approved                             |
| <input type="checkbox"/> IRB certification             | <input type="checkbox"/> Informed consent          | <input type="checkbox"/> Deficient final report                      |
| <input type="checkbox"/> Request hearing               | <input type="checkbox"/> Manufacturer              | <input type="checkbox"/> Deficient progress report                   |
| <input type="checkbox"/> Request waiver                | <input type="checkbox"/> Manufacturing             | <input type="checkbox"/> Deficient investigator report               |
| <input type="checkbox"/> Termination of study          | <input type="checkbox"/> Protocol-feasibility      | <input type="checkbox"/> Disapproval                                 |
| <input type="checkbox"/> Withdrawal of application     | <input type="checkbox"/> Protocol-other            | <input type="checkbox"/> Request extension of time to respond to FDA |
| <input type="checkbox"/> Unanticipated adverse effect  | <input type="checkbox"/> Sponsor                   | <input type="checkbox"/> Request meeting                             |
| <input type="checkbox"/> Emergency use:                | <input type="checkbox"/> Report submission:        | <input type="checkbox"/> IOL submission only:                        |
| <input type="checkbox"/> Notification of emergency use | <input type="checkbox"/> Current investigator      | <input type="checkbox"/> Change in IOL style                         |
| <input type="checkbox"/> Additional information        | <input type="checkbox"/> Annual progress           | <input type="checkbox"/> Request for protocol waiver                 |
| <input type="checkbox"/> Other reason (specify):       | <input type="checkbox"/> Site waiver limit reached |                                                                      |
|                                                        | <input type="checkbox"/> Final                     |                                                                      |

**Section C**

**Product Classification**

Product Code: 79 NBY

C.F.R. Section: 878.5035

Device Class:

- Class I     Class II  
 Class III     Unclassified

Classification Panel: General and Plastic Surgery

**Section D**

**Information on 510(k) Submissions**

Product codes of devices to which substantial equivalence is claimed:

1. 79 NBY	2.	3.	4.
5.	6.	7.	8.

Summary of, or statement concerning safety and effectiveness data:

- 510(k) summary attached  
 510(k) statement

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1. N/A	1. Gore-Tex™ e-PTFE Sutures	1. W.L. Gore & Associates
2.	2.	2.
3.	3.	3.
4.	4.	4.
5.	5.	5.
6.	6.	6.

**Section E**

**Product Information - Applicable to All Applications**

Common or usual name or classification name:

Suture, Nonabsorbable, Synthetic, Polytetrafluoroethylene

Trade or proprietary or model name	Model number
1. Cytoplast™ Suture	1. CS-0318
2. Cytoplast™ Suture	2. CS-0416
3. Cytoplast™ Suture	3. CS-0418
4. Cytoplast™ Suture	4. CS-0513
5. Cytoplast™ Suture	5. CS-0513PC
6. Cytoplast™ Suture	6. CS-0516HC

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

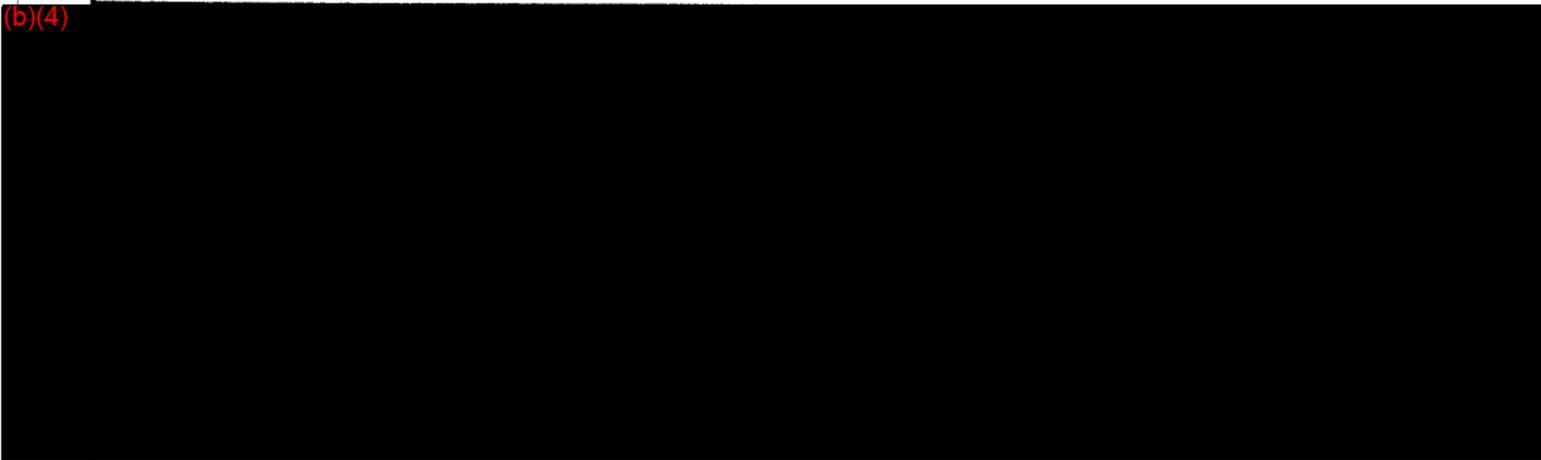
1.	2.	3.	4.	5.	6.
7.	8.	9.	10.	11.	12.

Data included in submission:     Laboratory testing     Animal trials     Human trials

Indications (from labeling):

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

		FDA Document Number:	
<b>Section F</b>		<b>Manufacturing / Packaging / Sterilization Sites</b>	
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number: 1650372	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer	<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager/relabeler
Company / Institution name: Osteogenics Biomedical, Inc.			
Division name (if applicable):		Phone number (include area code) 806-792-2311	
Street Address: 3234 - 64th Street		FAX number (include area code) 806-792-8730	
City: Lubbock	State / Province Texas	Country: USA	ZIP / Postal Code 79413
Contact name: Chad Bartee			
Contact title: President			



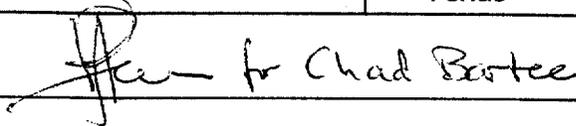
(b)(4)

Contact name:			
Contact title:			
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number:	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer	<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager/relabeler
Company / Institution name:			
Division name (if applicable):		Phone number (include area code) ( )	
Street Address:		FAX number (include area code) ( )	
City:	State / Province	Country:	ZIP / Postal Code
Contact name:			
Contact title:			

FDA Document Number:

**Section G**

**Applicant or Sponsor**

Company / Institution name: <b>Osteogenics Biomedical, Inc.</b>		FDA establishment registration number: <b>1650372</b>	
Division name (if applicable):		Phone number (include area code) <b>806-792-2311</b>	
Street Address: <b>3234 64th Street</b>		FAX number (include area code) <b>806-792-8730</b>	
City: <b>Lubbock</b>	State / Province <b>Texas</b>	Country: <b>USA</b>	ZIP / Postal Code <b>79431</b>
Signature: 			
Name: <b>Chad Bartee</b>			
Title: <b>President</b>			

**Section H**

**Submission correspondent (if different from above)**

Company / Institution name: <b>Richard Hamer Associates, Inc.</b>		Phone number (include area code) <b>817-294-3644</b>	
Division name (if applicable):		FAX number (include area code) <b>817-294-3761</b>	
Street Address: <b>6401 Meadows West Dr.</b>			
City: <b>Fort Worth</b>	State / Province <b>Texas</b>	Country: <b>USA</b>	ZIP / Postal Code <b>76132</b>
Contact name: <b>Richard A. Hamer</b>			
Contact title: <b>Consultant to Osteogenics Biomedical, Inc.</b>			



**VIA FEDERAL EXPRESS**

September 27, 2000

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

In Re: Cytoplast™ Sutures (Nonabsorbable n-PTFE Surgical Sutures)  
Osteogenics Biomedical, Inc., Lubbock, Texas 79413  
510 (k) Premarket Notification

Gentlemen:

In accordance with the requirements of 21 CFR 807.81, I am pleased to submit herewith, on behalf of Osteogenics Biomedical, Inc., Lubbock, TX, duplicate copies of a 510 (k) notification for the subject device.

Please note that Osteogenics Biomedical, Inc. considers the information provided in this submission to be proprietary and exempt from public disclosure under 21 CFR 20.61.

All data and information contained in this submission was furnished to us by Osteogenics Biomedical, Inc. To the best of our knowledge, it is truthful and accurate, and no material fact has been omitted.

I look forward to your favorable consideration of this premarket notification at your earliest convenience.

Sincerely,

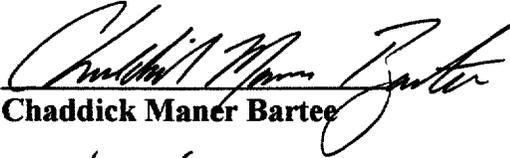
Richard A. Hamer  
Consultant to Osteogenics Biomedical, Inc.

cc: Mr. Chad Bartee, Osteogenics Biomedical, Inc.

5  
30

**PREMARKET NOTIFICATION  
TRUTHFUL AND ACCURATE STATEMENT  
(AS REQUIRED BY 21 CFR 807.87 (J))**

**I certify that, in my capacity as President of Osteogenics Biomedical, Inc., I believe, to the best of my knowledge, that all data and information submitted in this premarket notification is truthful and accurate and that no material fact has been omitted.**

  
Chaddick Maner Bartee

8/24/00  
Date

K \_\_\_\_\_

510(k) Number (if known): \_\_\_\_\_

Device Name: Cytoplast™ Sutures

**Indications for Use:**

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

(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 \_\_\_\_\_

(Optional Format 1-2-96)

## SECTION 1: GENERAL INFORMATION

---

**A. Device Name:**

**Proprietary Name:** Cytoplast™ Sutures

**Classification Name:** Suture, Nonabsorbable, Synthetic, Polytetrafluoroethylene

**B. Establishment Registration No.:** 1650372

**C. Addresses of Manufacturing and Sterilization Facility:**

Osteogenics Biomedical, Inc. (Manufacturer)  
3234 - 64th Street  
Lubbock, Texas 79431

(b) (4)



**D. Section 513 Classification:** Class II; 21 CFR §878.5035

**E. Reason for the Premarket Notification:** New Device

**F. Predicate Device:**

Gore-Tex™ e-PTFE Sutures (W.L Gore & Associates, Inc.)

**G. Performance Standards:**

The following FDA recognized consensus standards and labeling have been identified as special controls for this device (65FR20734-50):

(1) United States Pharmacopoeia (USP) 24:

- (i) Monograph for Nonabsorbable Surgical Sutures;
- (ii) Sutures - Diameter <861>
- (iii) Sutures Needle Attachment <871>; and
- (iv) Tensile Strength <881>

(2) Labeling:

- (i) Contraindication: "This device is contraindicated for use in ophthalmic and neural tissues and for use in microsurgery."
- (ii) "For Single Use Only"
- (iii) If the marketed suture has a different diameter than the diameter specified in USP 21 - Suture Diameter <861>, then a tabular comparison of its diameter and USP sizes should be included in the labeling.

## SECTION 2: 510 (k) SUMMARY

---

A 510(k) summary conforming to the content and format requirements specified in 21 CFR §807.92 is provided on the following pages:

## 510 (k) SUMMARY

### I. ADMINISTRATIVE

**Submitter:** Osteogenics Biomedical, Inc.  
3234 64th Street  
Lubbock, TX 79413  
(806) 792-2311

**Contact Person:** Chad Bartee

**Date of Preparation:** September 27, 2000

### II. DEVICE NAME

**Proprietary Name:** Cytoplast™ Suture

**Common Name:** Non-Absorbable n-PTFE Surgical Sutures

**Classification Name:** Suture, Nonabsorbable, Synthetic, Polytetrafluorethylene

### III. PREDICATE DEVICE

Gore-Tex™ e-PTFE Sutures; W.L Gore & Associates, Inc.

### IV. DEVICE DESCRIPTION

The Cytoplast™ Suture is a nonabsorbable, sterile surgical monofilament suture composed of polytetrafluoroethylene that has been expanded to produce a nanoporous microstructure (n-PTFE). The Cytoplast™ Suture meets all requirements in the USP 24 monograph for Nonabsorbable Surgical Sutures. The suture is undyed and contains no additives. The Cytoplast™ Suture is supplied sterile with attached standard surgical needles in a variety of sizes.

### V. INTENDED USE

The Cytoplast™ Suture is intended for use in the approximation and ligation of soft tissue in the oral cavity, including fixation of barrier membranes. The intended use of the predicate device, Gore-Tex™ e-PTFE Sutures, is broader, including cardiovascular surgery and dura mater repair. However, Osteogenics Biomedical has limited the intended use to the dental surgical market in which it operates.

**VI. COMPARISON TO PREDICATE DEVICE**

	<b>Cytoplast™ n-PTFE Suture</b>	<b>Predicate Device</b>
Intended Use:	Approximation and ligation of soft tissue in the oral cavity, including fixation of barrier membranes.	Soft tissue approximation and/or ligation, including use in cardiovascular surgery and dura mater repair.
Suture material:	Polytetrafluoroethylene (100%); expanded	Polytetrafluoroethylene (100%); expanded
Suture Characteristics:	Not absorbed and no significant changes known to occur <i>in vivo</i> .	Not absorbed and no significant changes known to occur <i>in vivo</i> .
How Supplied:	Sterile monofilament thread, undyed, 24-inches long in various sizes with attached needles.	Sterile monofilament thread, undyed, 24-inches long in various sizes with attached needles.
Use (single, reusable, disposable)	Single Use Only.	Single use Only.
Suture Diameter Suture Length Needle Attachment Strength Knot Pull Tensile Strength	Meets U.S.P. requirements.	Differs from U.S.P. requirements in diameter and knot-pull tensile strength.
Packaging	Dry packaged in paper/polyester-polypropylene tear-open pouch.	Same or equivalent manner.

Based on this comparison, Osteogenics Biomedical, Inc. concludes that the Cytoplast™ Suture is safe and effective for its intended use and performs at least as well as the predicate device.

### SECTION 3: PROPOSED LABELING

---

Copies of proposed pouch label and package insert for the Cytoplast™ Sutures are provided on the following pages:

Pouch Label

STERILE  
FOR SINGLE USE ONLY

LOT:

**Cytoplast™ Suture**  
**n-PTFE Nonabsorbable Monofilament Suture, U.S.P**

(Model #, Dimensions)

See Instructions for Use

Osteogenics Biomedical, Inc.  
Lubbock, Texas 79413

## Package Insert

### **Cytoplast™ Sutures** **n-PTFE Nonabsorbable Monofilament Suture, U.S.P.**

#### **Description**

The Cytoplast™ Suture is a nonabsorbable, monofilament suture manufactured from polytetrafluoroethylene that has been expanded to produce a nanoporous microstructure (n-PTFE). The porous nature of the n-PTFE enables it to be swaged to needles that closely approximate the diameter of the thread, without compromising the strength of the needle attachment. The suture is undyed and contains no additives. The Cytoplast™ Suture meets all USP requirements.

#### **Actions**

PTFE has been shown in clinical trials to elicit minimal tissue reaction. The Cytoplast™ Suture is not absorbed or subject to weakening by the action of tissue enzymes.

The internodal spaces of n-PTFE permit infiltration of fibroblasts and leukocytes. Tissue attaches to and collagen penetrates into the Cytoplast™ Suture. The micro-porous structure of the suture does not allow bacteria to invade the suture itself, decreasing inflammation around suture lines.

#### **Indications**

The Cytoplast™ Suture is indicated for use in approximation and ligation of soft tissue in the oral cavity, including fixation of barrier membranes.

#### **Contraindications**

This device is contraindicated for use in ophthalmic surgery, microsurgery, and peripheral neural tissue.

#### **Warnings**

Tissue invasion of the n-PTFE suture can result in attachment of the suture to the tissue it penetrates. Such attachment may make removal of the suture difficult.

### **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.

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™ Suture, tension should be applied by pulling each strand of the suture in opposite directions with equal force. 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. Uneven tensioning of a well-formed square knot may result in an unsecure knot. When the Cytoplast™ Suture is properly tensioned and formed, standard surgical knotting techniques will produce a secure knot.

### **Sterility**

Cytoplast™ Sutures are supplied STERILE unless the integrity of the package has been compromised. This 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 tissue reaction.

### **Dosage and Administration**

Use as required per surgical procedure.

### How Supplied

Cytoplast™ Sutures are available as sterile strands, 24 inches (61 cm) long with permanently attached needles in the following sizes:

Model	Needle	USP Sizes
CS-0318	18 mm reverse cutting 3/8 Circle, FS-2	3.0
CS-0416	16 mm reverse cutting 3/8 Circle, FS-2	4.0
CS-0418	18 mm reverse cutting 3/8 Circle, FS-2	4.0
CS-0513	13mm reverse cutting 3/8 Circle, P-3	5.0
CS-0516HC	16mm reverse cutting 1/2 Circle, PS-4	5.0
CS-0513PC	13mm piercing point 1/2 Circle	5.0

For single use only.

**Osteogenics Biomedical, Inc.**  
**Lubbock, Texas 79413**

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## SECTION 4: DEVICE DESCRIPTION

The Cytoplast™ Nonabsorbable Suture is composed of [REDACTED], [REDACTED], (b) [REDACTED], nanoporous polytetrafluoroethylene [REDACTED], (b) [REDACTED]

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

[REDACTED]

Cytoplast™ Nonabsorbable n-PTFE Sutures are (b)(4)Trade Secret Process-Product Specs

(b) [REDACTED] 24 inches long, and will be supplied with attached surgical needles in the following configurations and sizes:  
(4)Trade

Model	Needle	Gore Equivalent	USP Sizes
CS-0318	18 mm reverse cutting 3/8 Circle, FS-2	P4K 13	3.0
CS-0416	16 mm reverse cutting 3/8 Circle, FS-2	P5K17	4.0
CS-0418	18 mm reverse cutting 3/8 Circle, FS-2	P5K23	4.0
CS-0513	13 mm reverse cutting 3/8 Circle, P-3	P6K23	5.0
CS-0516HC	16 mm reverse cutting 1/2 Circle, PS-4	P6K25	5.0
CS-0513PC	13 mm piercing point 1/2 Circle	P6K13	5.0

Stainless steel needles are manufactured and supplied by [REDACTED], [REDACTED], (b) (4) [REDACTED].  
needle equivalents to the above needles are as follows:

Code	Description	(b)(4)Trade Secret Process-Product Specs (b)(4)Trade Secret Process-Product Specs
FS-2	Reverse Cutting 3/8 Circle, 18 & 16mm	

4217

P-3 Reverse Cutting 3/8 Circle, 13mm  
 PS-4 Reverse Cutting, 1/2 Circle, 16mm  
 Custom Tapered Point 1/2 Circle

(b)(4)Trade Secret  
 (b)(4)Trade Secret  
 S I P  
 (b)(4)Trade Secret  
 Process Product

Stainless steel specifications are provided on page 22.

Sutures will be individually packaged in paper and polyester/polypropylene pouches prior to steam sterilization. (b) (4)

(b) (4)

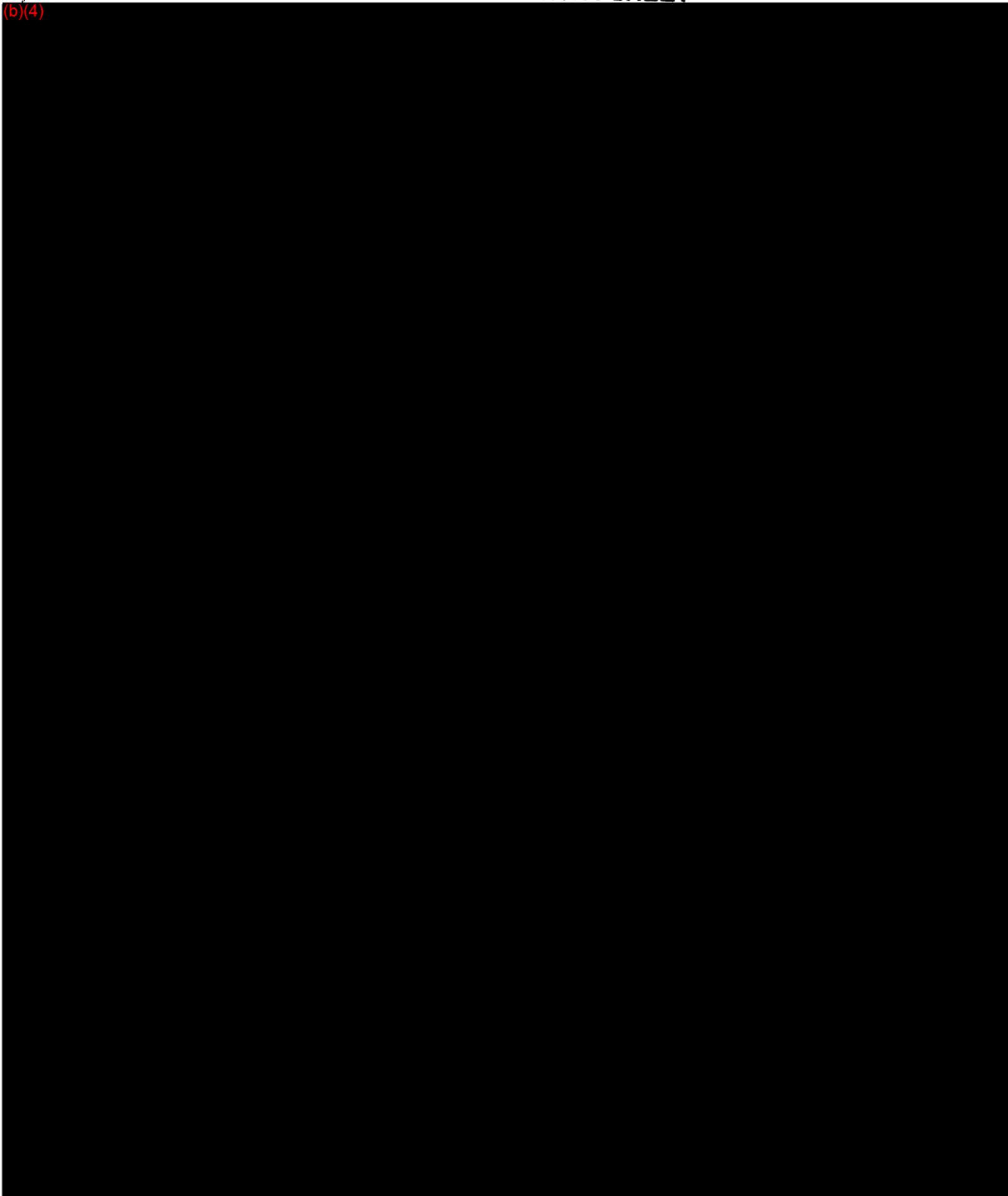
Samples of the Cytoplast n-PTFE sutures have been tested for compliance with USP XXIV requirements for Nonabsorbable Surgical Sutures and were found to meet USP requirements for suture diameter, knot-pull tensile strength and needle attachment strength. Results are summarized below. (b) (4)

(b) (4)

Suture Size	Suture Diameter (mm)		Knot-Pull Tensile Strength (Kgf)		Needle Attachment Strength (Kgf)	
	Mean	USP Limits	Mean	USP Limit Min.	Mean	USP Limit Min.
5-0	(b) (4)	0.10 - 0.149	(b) (4)	0.40	(b) (4)	0.23
4-0	(b) (4)	0.15 - 0.199	(b) (4)	0.60	(b) (4)	0.45
3-0	(b) (4)	0.20 - 0.249	(b) (4)	0.96	(b) (4)	0.68

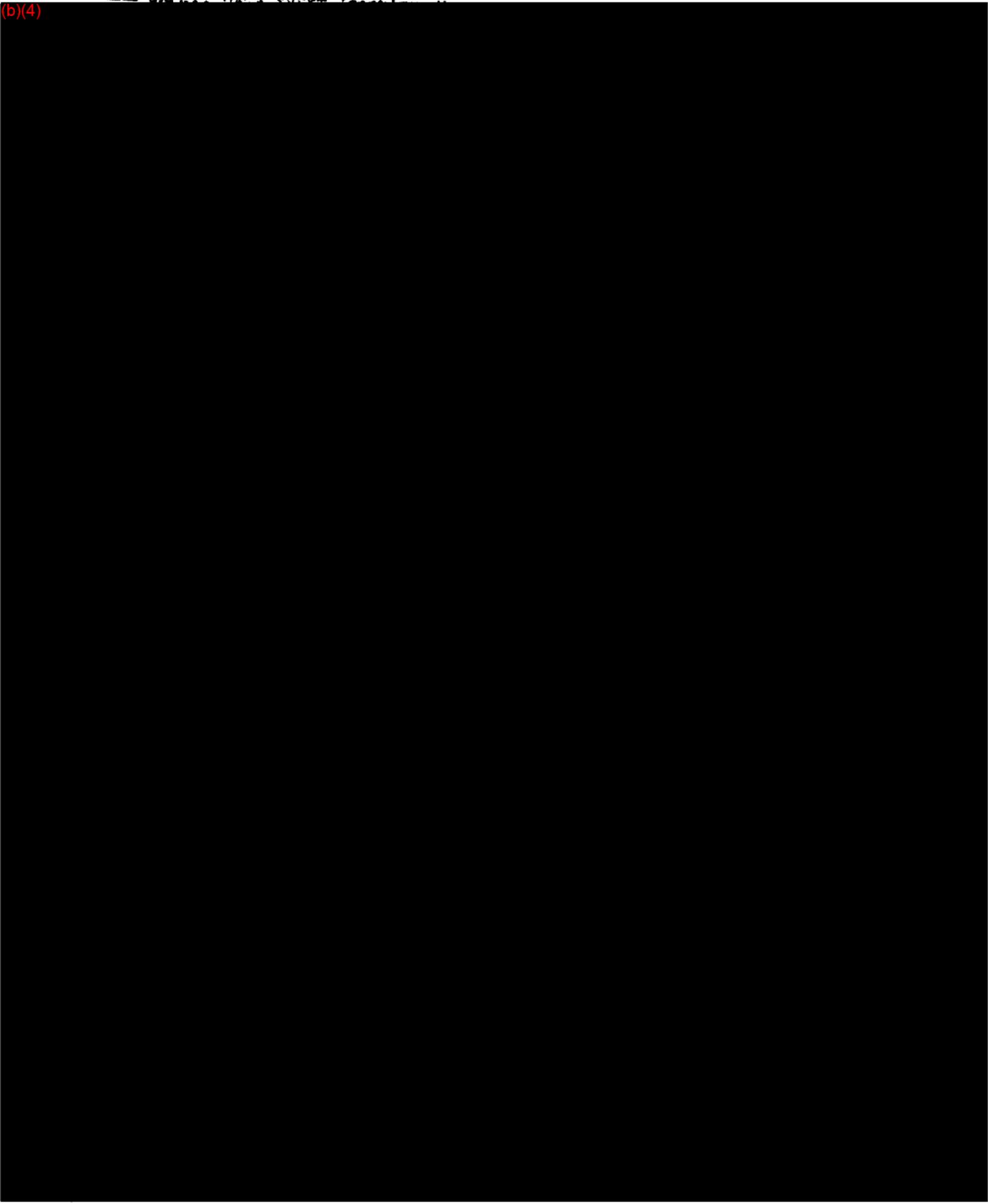
MATERIAL SAFETY DATA SHEET

(b)(4)

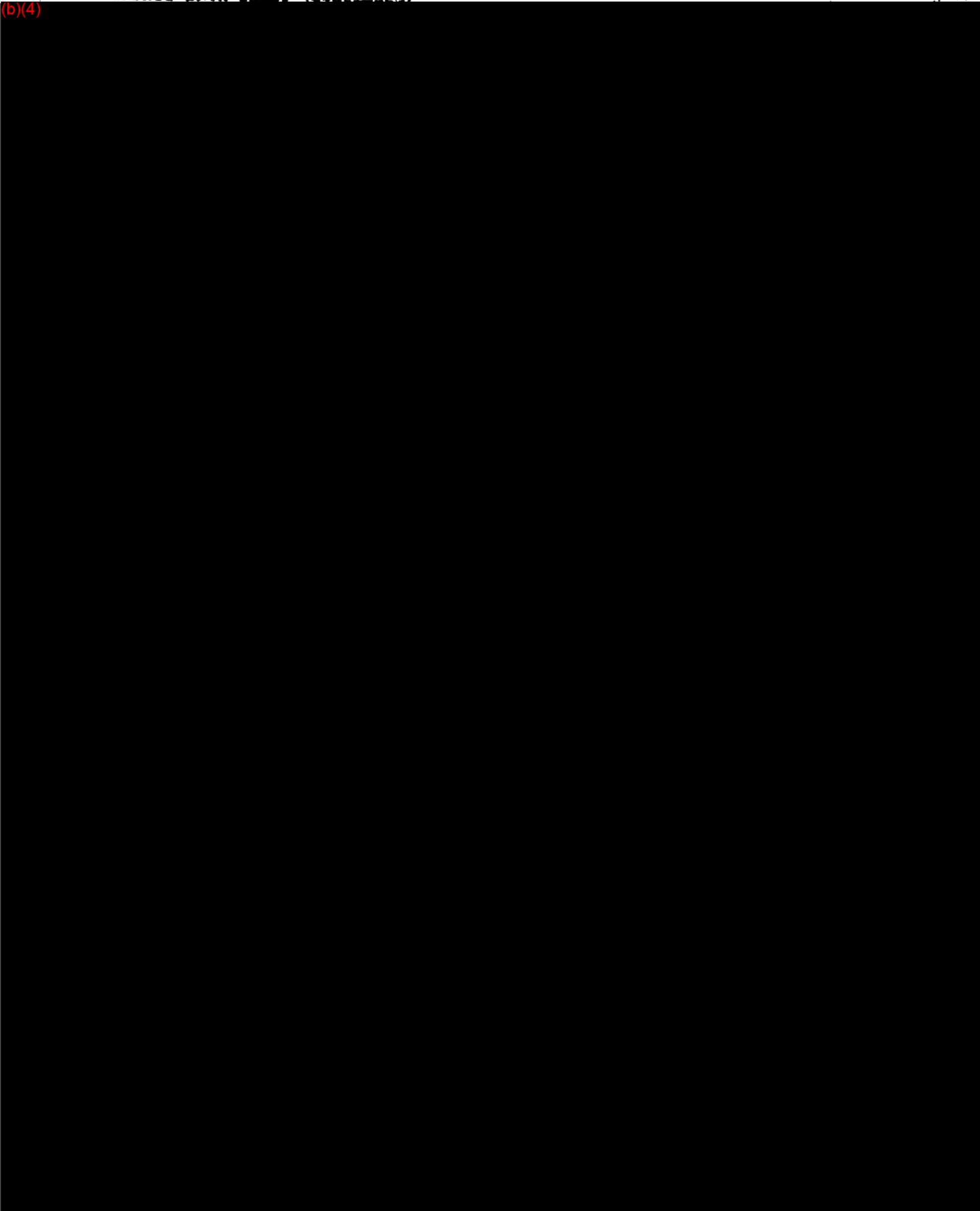


MATERIAL SAFETY DATA SHEET (MSDS)

(b)(4)



(b)(4)



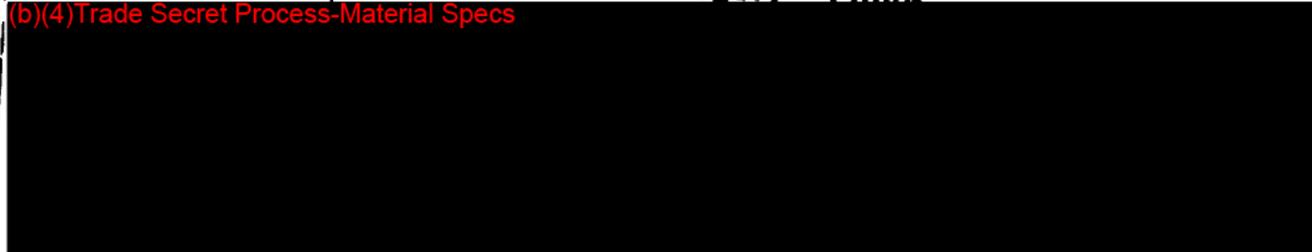






# Material Specification #2018 Category - Films

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



## 1.0 Description

1.1 Blue tint polyester - polypropylene lamination. Clear polyester sheeting on the outside, clear polypropylene on the inside. laminated together with blue tint adhesive.

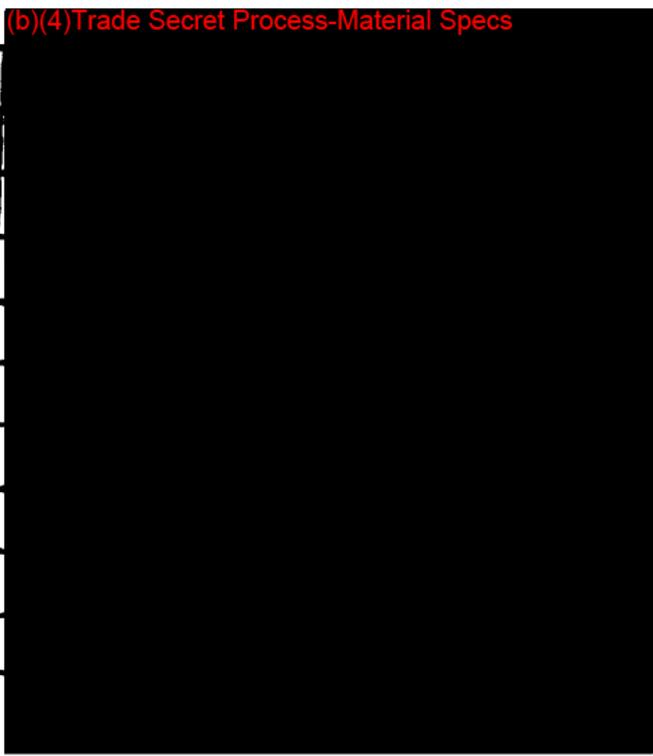
## 2.0 Physical Specifications

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



Property	Test Method
2.2 Total material	T411-OS-88
2.3 Polyester material	T411-OS-88
2.4 Polypropylene material	T411-OS-88
2.5 Porosity	T460-OS-88
2.6 Yield	Yield Table
2.7 Interply bond strength	Manual
2.8 Tint	PMS Color Chart Visual
2.9 Width	Ruler
2.10 Maximum roll size	Ruler
2.11 Core size	Ruler

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



SD  
25

### Osteogenics

#### 5-0 EPTFE monofilament

#### Knot-Pull

Company: (b) [REDACTED]  
Lab name: (4)T OBI Research and Development  
Operator ID:  
Test date: 9/20/00

Name:  
Number of specimens: 5  
Temperature: 25 +/- 3 C  
Humidity: 40% +/- 10%  
Speed 1: 10.00 mm/min

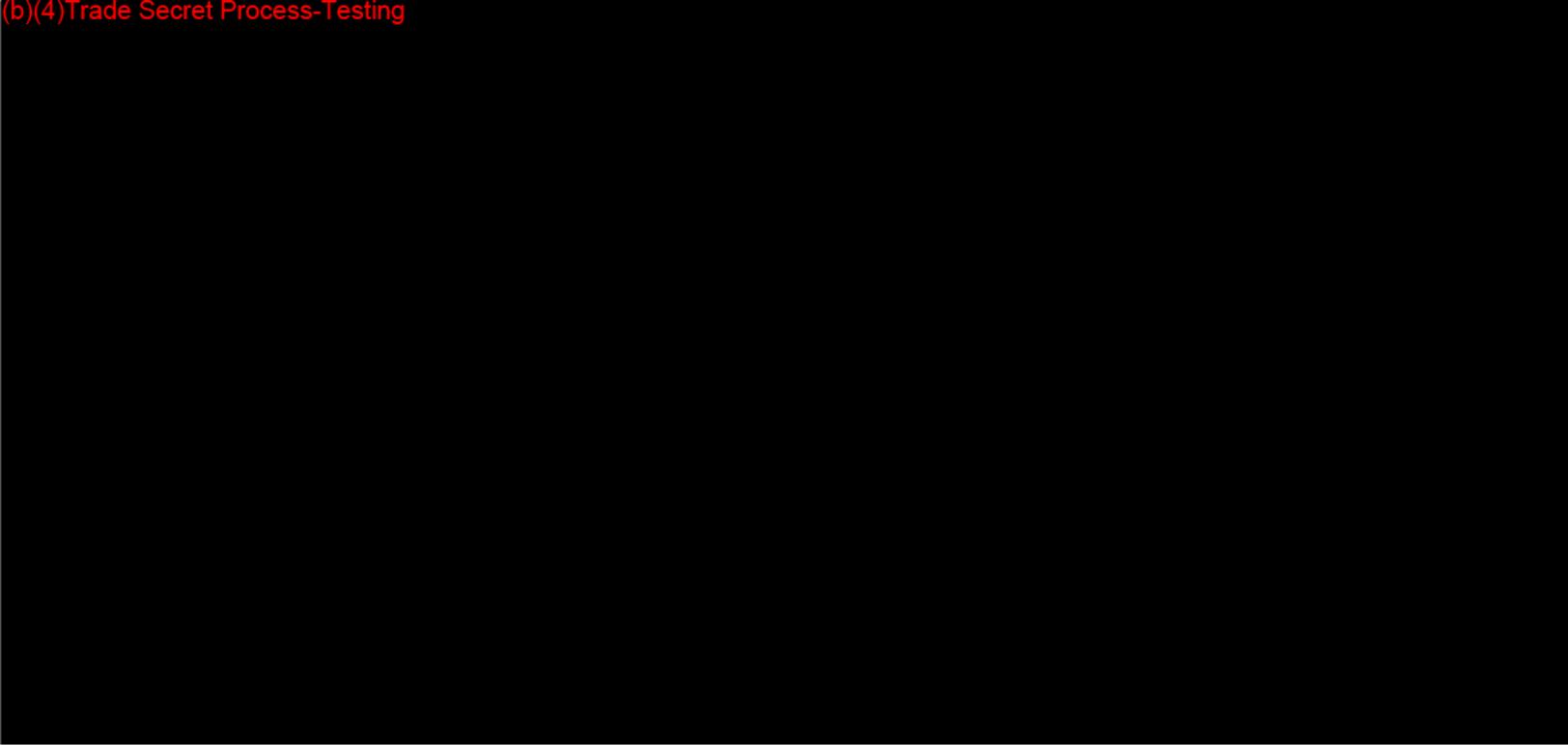
Note 1:

Note 2:

Note 3:

(b)(4)Trade Secret Process-Testing





**Osteogenics**

**4-0 EPTFE monofilament**

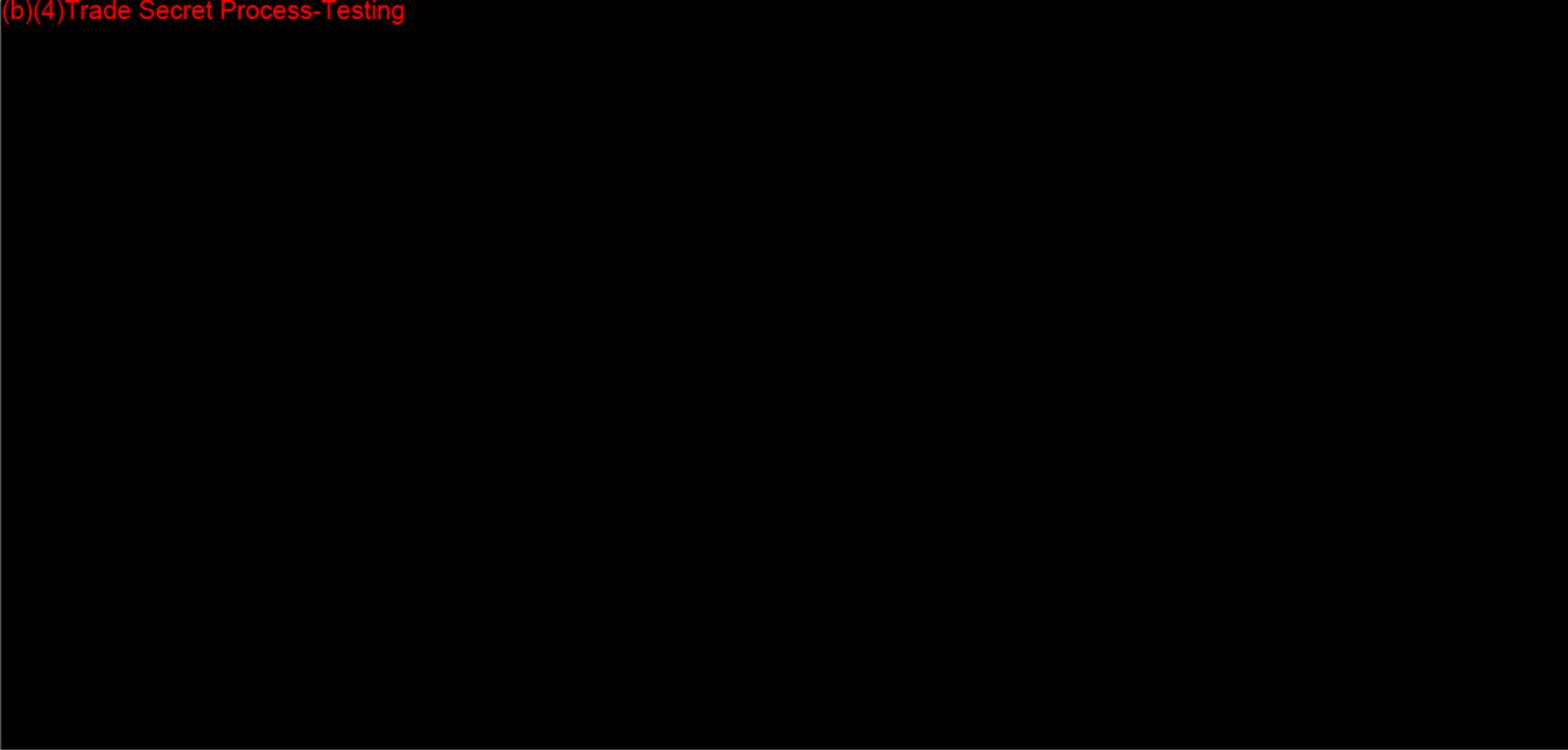
**Knot-Pull**

Company: (b)(4)Trade Secret  
Lab name: OBI Research and Development  
Operator ID:  
Test date: 9/20/00

Name:  
Number of specimens: 5  
Temperature: 25 +/- 3 C  
Humidity: 40% +/- 10%  
Speed 1: 10.00 mm/min

Note 1:  
  
Note 2:  
  
Note 3:





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### Osteogenics

#### 3-0 EPTFE monofilament

#### Knot-Pull

Company: (b) [REDACTED]  
Lab name: (4)T d OBI Research and Development  
Operator ID:  
Test date: 9/19/00

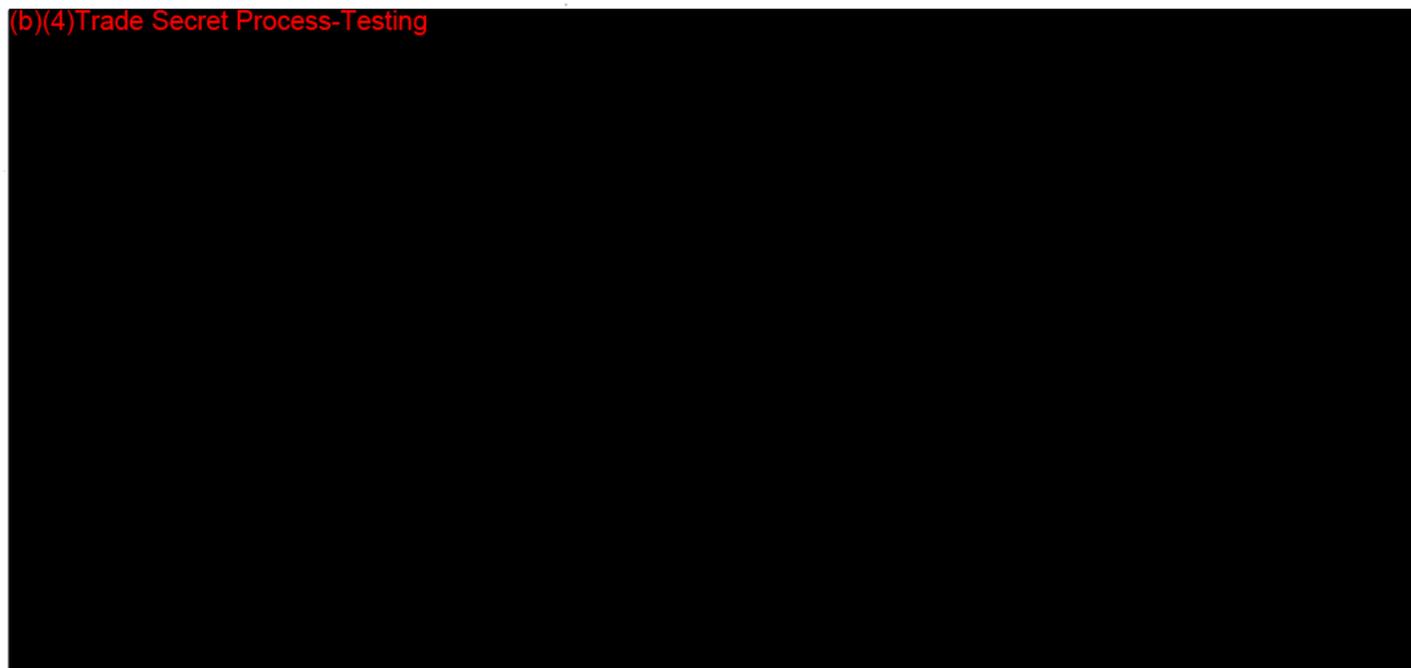
Name:  
Number of specimens: 5  
Temperature: 25 +/- 3 C  
Humidity: 40% +/- 10%  
Speed 1: 10.00 mm/min

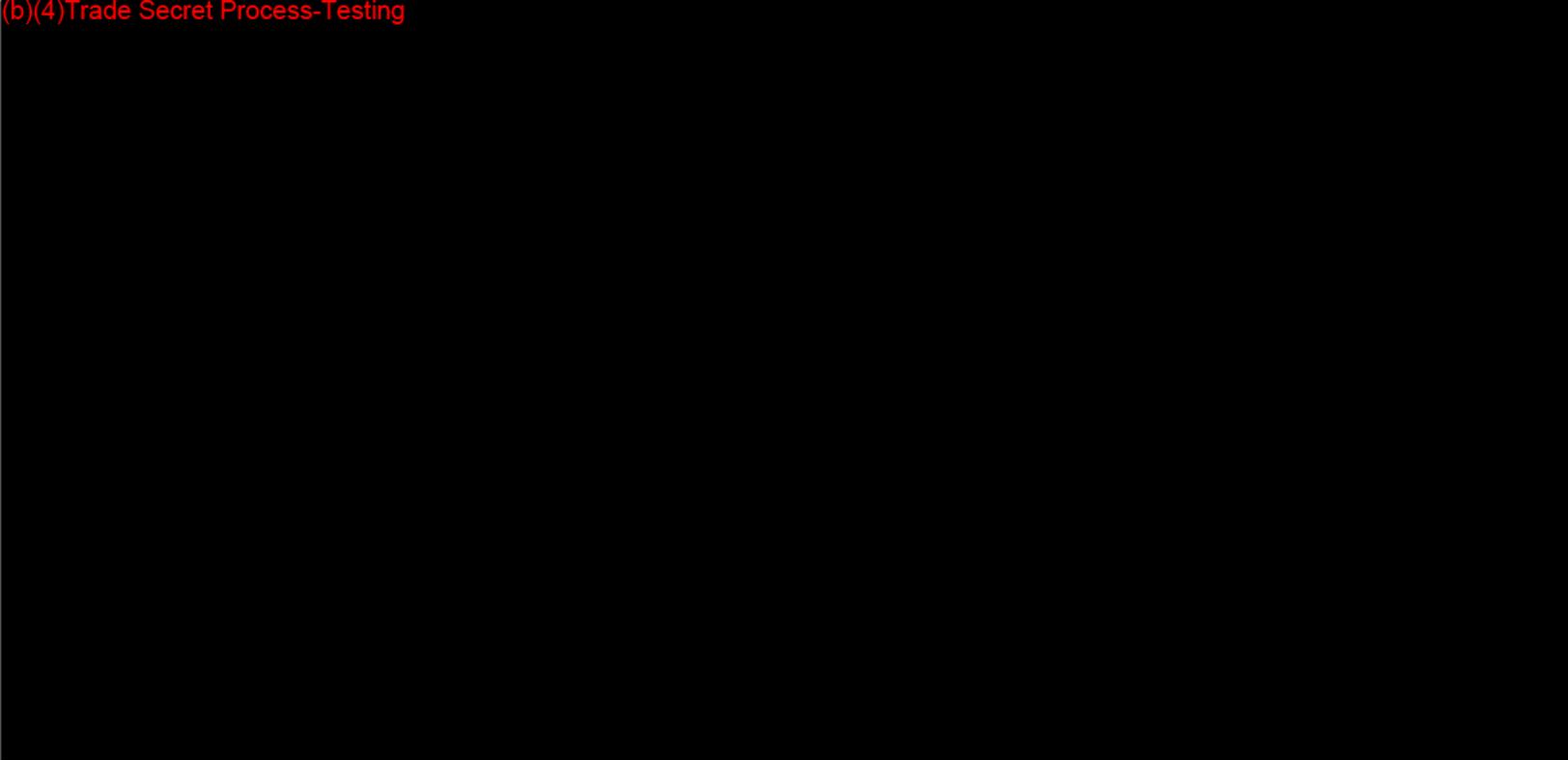
Note 1:

Note 2:

Note 3:

(b)(4)Trade Secret Process-Testing





sb

**Osteogenics**

**5-0 EPTFE monofilament**

**Needle attachment**

Company: (b)(4)Trade Secret  
Lab name: OBI Research and Development  
Operator ID:  
Test date: 9/20/00

Name:  
Number of specimens: 5  
Temperature: 25 +/- 3 C  
Humidity: 40% +/- 10%  
Speed 1: 10.00 mm/min

Note 1:

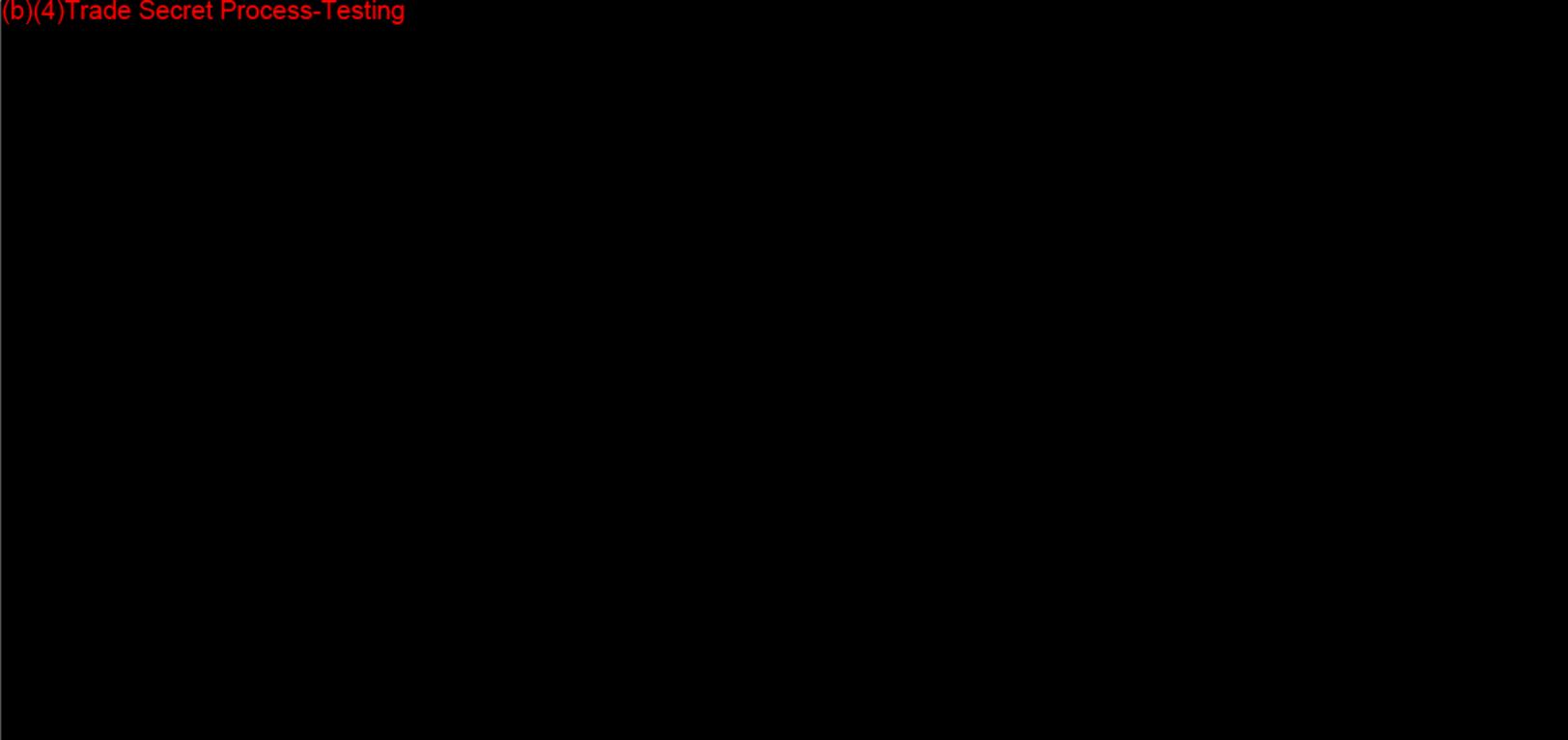
Note 2:

Note 3:

(b)(4)Trade Secret Process-Testing



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**Osteogenics**

**4-0 EPTFE monofilament**

**Needle attachment**

Company: (b)(4)Trade Secret  
Lab name: OBI Research and Development  
Operator ID:  
Test date: 9/20/00

Name:  
Number of specimens: 5  
Temperature: 25 +/- 3 C  
Humidity: 40% +/- 10%  
Speed 1: 10.00 mm/min

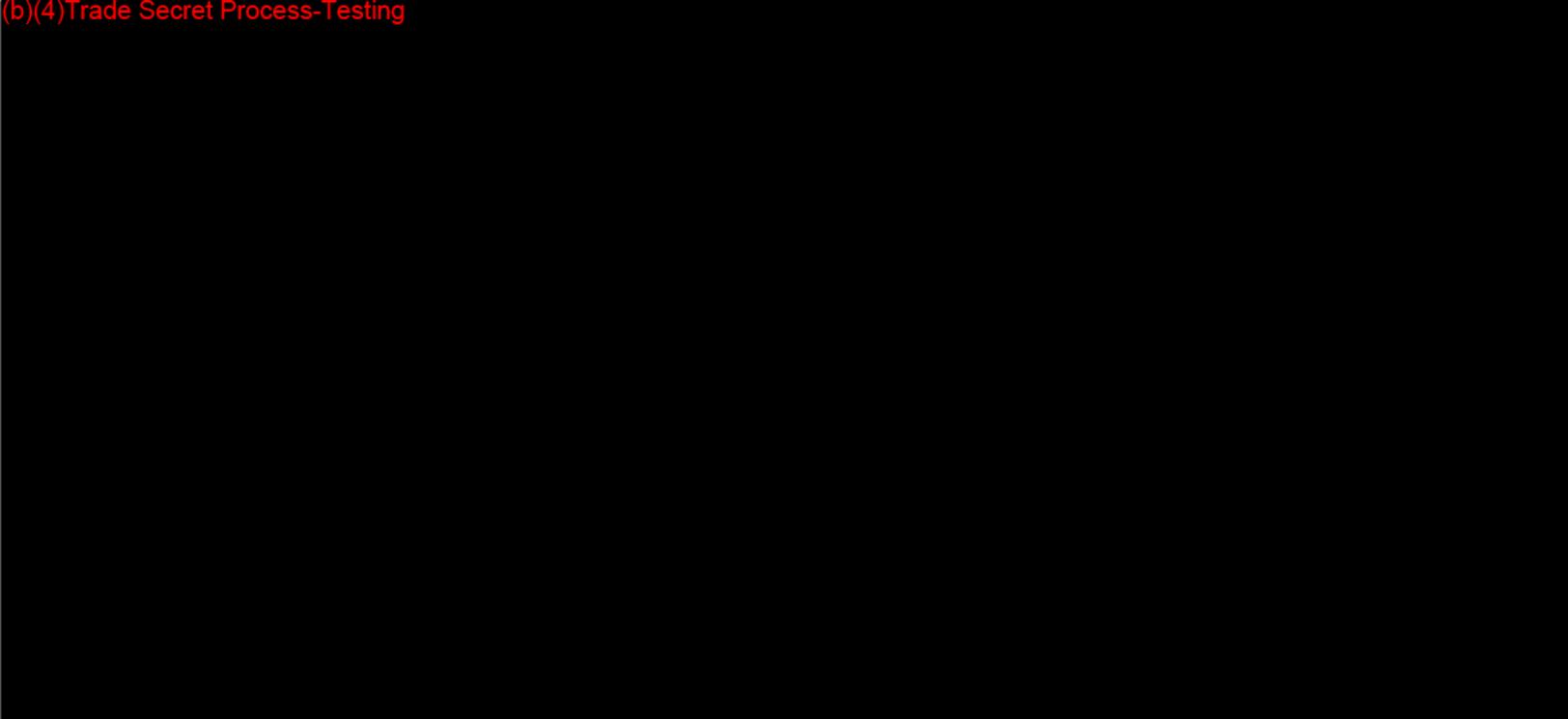
Note 1:

Note 2:

Note 3:

(b)(4)Trade Secret Process-Testing

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**Osteogenics**

**3-0 EPTFE monofilament**

**Needle attachment**

Company: (b)(4)Trade Secret  
Lab name: OBI Research and Development  
Operator ID:  
Test date: 9/19/01

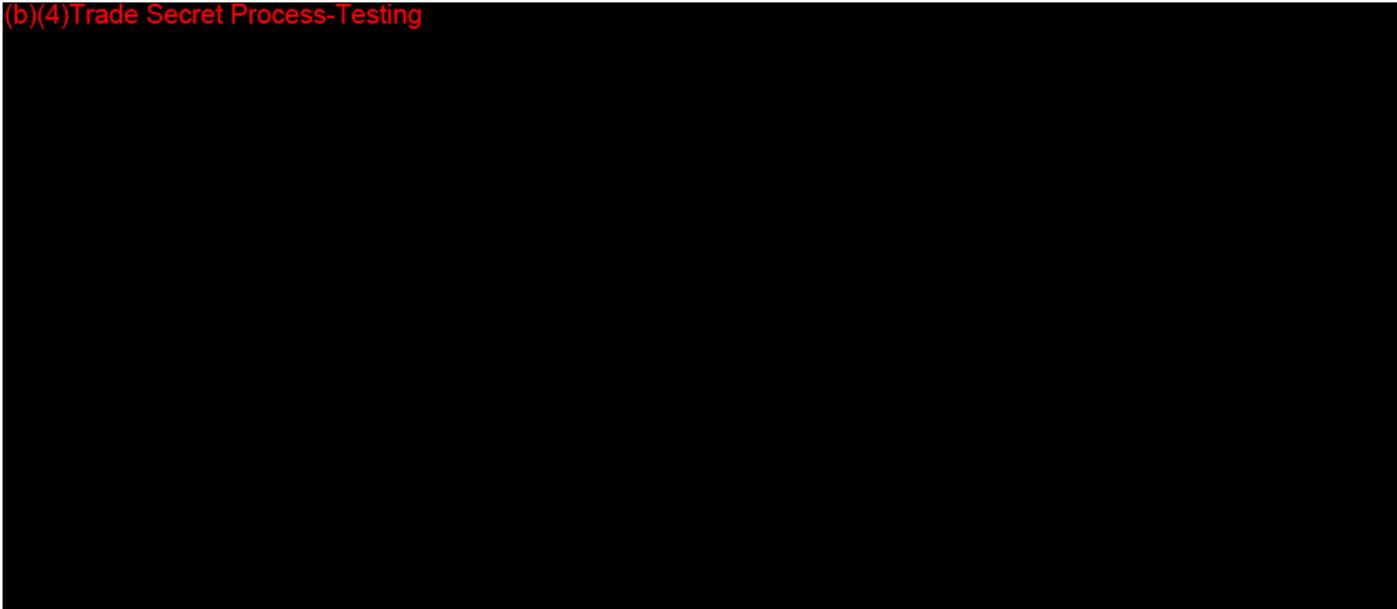
Name:  
Number of specimens: 5  
Temperature: 25 +/- 3 C  
Humidity: 40% +/- 10%  
Speed 1: 10.00 mm/min

Note 1:

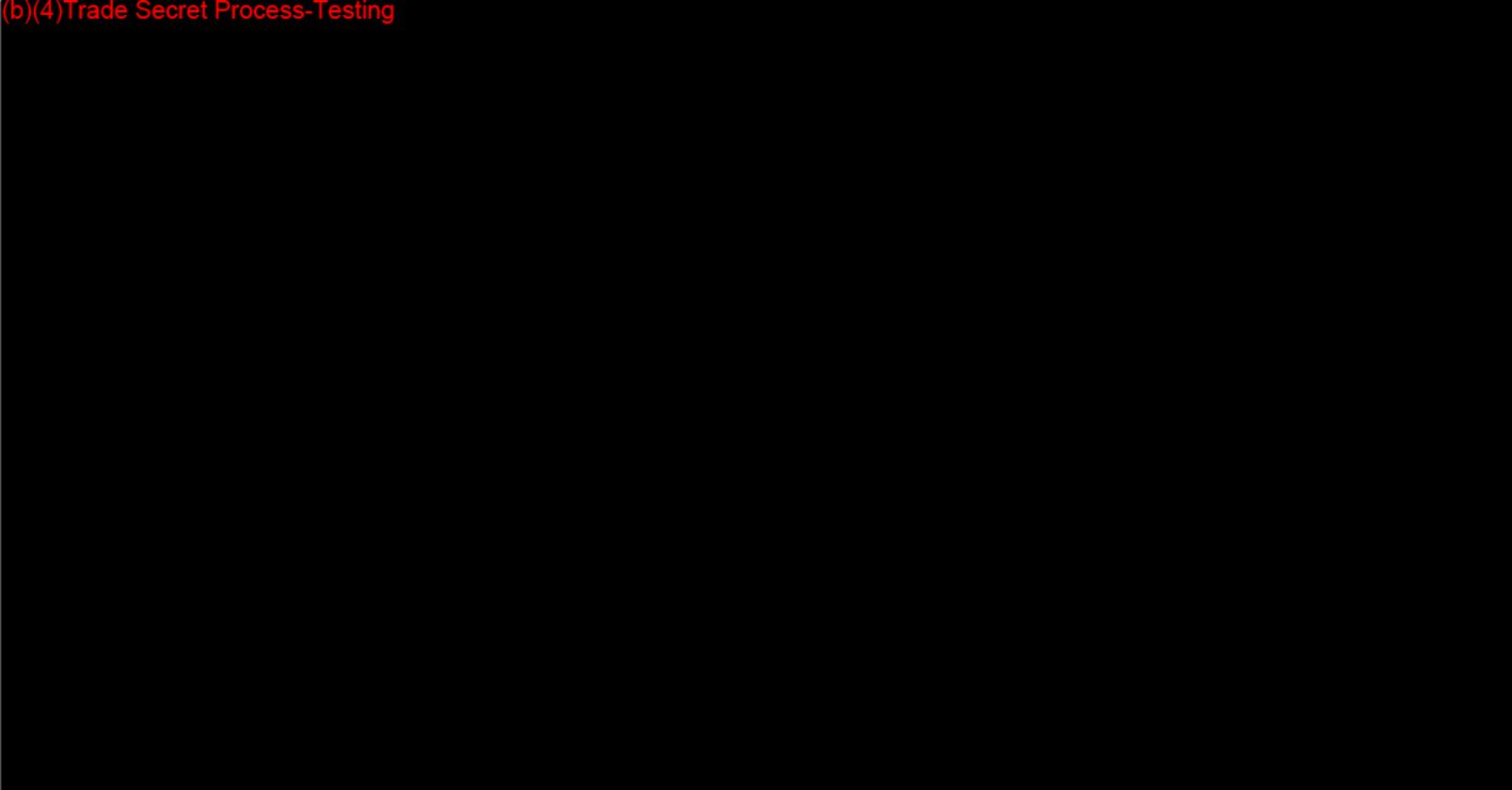
Note 2:

Note 3:

(b)(4)Trade Secret Process-Testing



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## SECTION 5: COMPARATIVE INFORMATION

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### A. Statement of Equivalence:

For purposes of Section 510 (k) of the Federal Food, Drug, and Cosmetic Act, Osteogenics Biomedical, Inc. considers the Cytoplast™ Nonabsorbable n-PTFE Sutures to be substantially equivalent to similar devices such as Gore-Tex™ e-PTFE Sutures (W.L. Gore & Associates) initially placed in commercial distribution pursuant to approved PMA P820083 and reclassified as a Class II device effective May 18, 2000. (21 CFR §878.5035; 65FR20734, April 18, 2000). As shown in the tabular comparison on the following page, these devices are similar in composition, design and function. The only substantial differences are: 1) the Cytoplast™ Sutures are manufactured to meet USP specifications for nonabsorbable surgical sutures; and 2) Osteogenics Biomedical has elected to limit the indications for use to the dental surgical market in which it competes. Neither difference precludes a finding of substantial equivalence.

**Table of Comparison to Legally Marketed Device**

	<b>Cytoplast™ n-PTFE Suture</b>	<b>Gore-Tex™ e-PTFE Suture P820083</b>
<b>Intended Use:</b>	Approximation and ligation of soft tissue in the oral cavity, including fixation of barrier membranes.	Soft tissue approximation and/or ligation, including use in cardiovascular surgery and dura mater repair.
<b>Suture material:</b>	Polytetrafluoroethylene (100%); expanded	Polytetrafluoroethylene (100%); expanded
<b>Suture Characteristics:</b>	Not absorbed and no significant changes known to occur <i>in vivo</i> .	Not absorbed and no significant changes known to occur <i>in vivo</i> .
<b>Sterilization Method:</b>	Steam	Same or equivalent process
<b>How Supplied:</b>	Sterile monofilament thread, undyed, 24-inches long in various sizes with attached needles.	Sterile monofilament thread, undyed, 24-inches long in various sizes with attached needles.
<b>Use (single, reusable, disposable)</b>	Single Use Only	Single use Only
<b>Suture Diameter Suture Length Needle Attachment Strength Knot Pull Tensile Strength</b>	Meets U.S.P. requirements	Differs from U.S.P. requirements in diameter and knot-pull tensile strength.
<b>Packaging</b>	Dry packaged in paper/polyester-polypropylene tear-open pouch.	Same or equivalent manner.

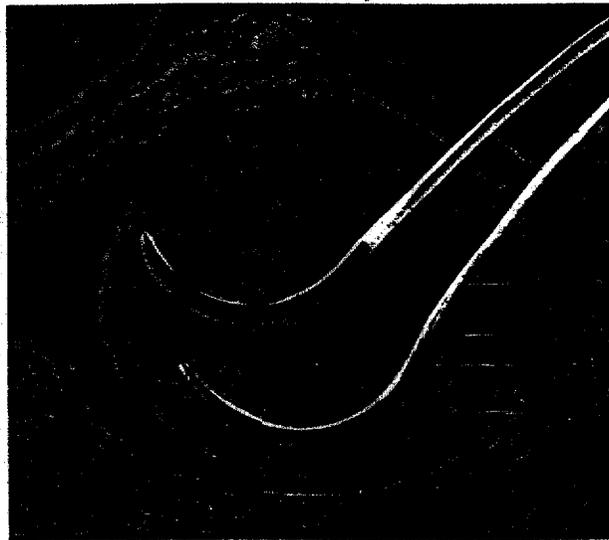
## SECTION 5: COMPARATIVE INFORMATION (continued)

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### B. Comparative Labeling:

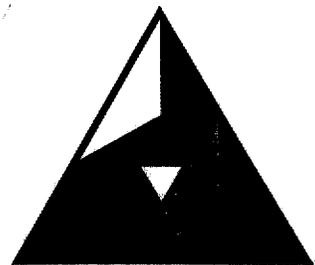
Copies of available labeling for Gore-Tex™ e-PTFE Sutures (W.L. Gore & Associates) are provided on the following pages:

**SUPERIOR HANDLING WITHOUT SACRIFICING  
TISSUE TOLERANCE:  
THE BEST OF BOTH WORLDS**



**GORE  
SUTURES**

In the past, clinicians had to choose between a suture with good handling properties and a suture tolerated well by tissue. Today, the trade-off is not necessary. All GORE Sutures offer superior handling and biocompatibility. For high-value applications, clinicians can now choose inert GORE-TEX Sutures or bioabsorbable GORE RESOLUT Sutures.



**G O R E  
REGENERATIVE  
TECHNOLOGIES**



GORE SUTURES

CV 4 -  
CV 5 -  
CV 6 -

### GORE-TEX® SUTURES

- **Tissue Tolerance.** The biocompatibility and inertness of GORE-TEX e-PTFE (expanded polytetrafluoroethylene) allows for GORE-TEX Sutures to remain in the oral environment for as long as two to four weeks.
- **Handling.** Low friction and the smooth, supple nature of GORE-TEX Sutures allow for superior handling and provide flexibility in the positioning of a square knot.
- **Nonwicking.** The monofilament GORE-TEX Suture is not subject to bacterial wicking sometimes associated with multifilament sutures.

### Configurations and Applications

Jocelyn  
7364

1605

664

1039

302

308

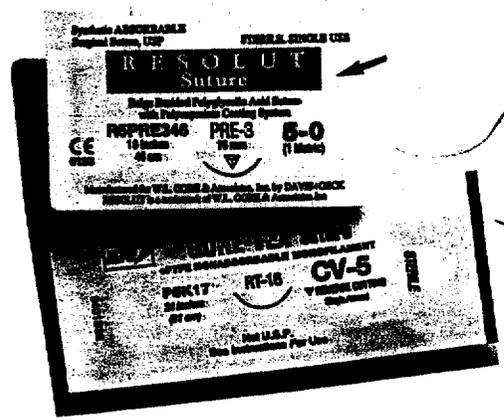
- P5K17**  A CV-5 suture with a 16 mm reverse-cutting needle. This is the standard GORE-TEX Suture provided with every piece of GORE Regenerative Materials. Many clinicians also select it for dental implant procedures or flap procedures in which they would prefer to leave the sutures in place for extended periods of time.
- P5K23**  A CV-5 suture with an 18 mm reverse-cutting needle. This can be used as an alternative to the P5K17 where a longer needle is preferred.
- P4K13**  A CV-4 suture with an 18 mm reverse-cutting needle. This can be used as an alternative to the P5K23 where a thicker suture is desired.
- P6K23**  A CV-6 suture with a 13 mm reverse-cutting needle. This is a finer suture with a smaller needle for delicate procedures such as gingival grafts or mucosal suturing.
- P6K25**  A CV-6 suture with a 16 mm reverse-cutting needle. This can be used as an alternative to the P6K23 where a 1/2 circle needle is preferred.
- P6K13**  A CV-6 suture with a 13 mm piercing point needle. This can be used where the clinician desires a piercing point needle to minimize tissue trauma.

### 5-0 GORE RESOLUT SUTURES

- **Bioabsorbability.** GORE RESOLUT Sutures are PGA (polyglycolic acid) sutures which absorb by hydrolysis.
- **Handling.** GORE RESOLUT Sutures exhibit minimal out-of-package memory and are coated with Polycaprolate for ease of handling and smooth tissue passage.
- **Patient Comfort.** The bioabsorbability of GORE RESOLUT Sutures can be a benefit in cases where the suture is intended to remain submerged, or in situations where removal of the suture might cause added trauma to the patient.

### Configurations and Applications

- R5PRE345**  A 5-0 suture with a 16 mm reverse-cutting needle. This is a bioabsorbable suture with a needle equivalent to the standard GORE-TEX Suture.
- R6PRE245**  A 6-0 suture with a 13 mm reverse cutting needle. This is a finer bioabsorbable suture with a smaller needle for delicate procedures such as gingival grafts or mucosal suturing.
- R5PR245**  A 5-0 suture with a 13 mm reverse cutting needle. This can be used as an alternative to the R6PRE245 where a 1/2 circle needle is preferred.



## GORE REGENERATIVE TECHNOLOGIES

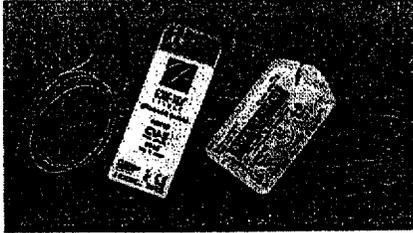
**3i** IMPLANT INNOVATIONS®  
4555 Riverside Drive  
Palm Beach Gardens, FL 33410

For complete information, contact:  
3i Customer Service  
Monday-Friday 8am-8pm (EST)  
800-342-5454 • 561-776-1272 Fax  
In Canada: 800-363-1980  
Outside U.S.: 561-776-6700

“3i” and “Implant Innovations” are registered trademarks of Implant Innovations, Inc.

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## GORE Suture



GORE-TEX®, GORE RESOLUT®, GORE and design are trademarks of W. L. Gore & Associates

## GORE-TEX Suture

- Pure ePTFE (expanded polytetrafluoroethylene)
  - Biocompatible and inert, can be left in the oral environment for extended periods of time (2-4 weeks) with outstanding tissue tolerance
  - Low friction and smooth nature of product allows for superior handling and flexibility in positioning a square knot.
  - Monofilament suture is not subject to bacterial wicking.

## GORE RESOLUT Suture

- Polyglycolic Acid (PGA) with Polycaprolate Coating
  - Absorb by hydrolysis
  - Minimal out-of-package memory due to polycaprolate coating
  - Smooth tissue passage
  - A benefit in cases where suture is intended to remain submerged (i.e., periosteal suturing) or in situations where suture removal would cause added trauma to patient

## GORE Sutures

- Both GORE-TEX Suture and GORE RESOLUT Suture are available for sale separately
- Both come in a variety of configurations to suit various applications (See Suture Flyer in Binder)
- See your binder for a chart showing how our GORE Sutures stack up against the competition!

## GORE-TEX Suture vs. GORE RESOLUT SUTURE

- |                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"><li>■ GORE-TEX Suture<ul style="list-style-type: none"><li>- Should always be used to close the flaps.</li><li>- Should be used wherever the suture will need to be in place for an extended period of time.</li><li>- Use this suture when you don't want to compromise an implant because of a suture complication.</li></ul></li></ul> | <ul style="list-style-type: none"><li>■ GORE RESOLUT Suture<ul style="list-style-type: none"><li>- Should not be used to close flaps</li><li>- TE-7 Needle (kit) should not be used to suture tissue due to needle type.</li><li>- Various configurations of sutures including a very fine suture which is ideal for grafting procedures. (See Suture Flyer in Binder)</li></ul></li></ul> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

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**GORE-TEX  
SUTURE**

CV-4 CV-5 CV-6

PK13  
VSK13  
PSK23  
PSK25  
PK13

**RESOLUT  
SUTURE**

4-0 5-0 6-0

R47B245  
RSPRE345  
RSPR245  
RPRE245

**GORE-TEX  
SUTURE NEEDLES**

Reverse Cutting  
3/8 Circle

RT-18  
PSK23  
PK13  
RT-16  
PSK17  
RT-13  
PK23  
RH-16  
PK25  
RH-13  
PK13  
RH-13  
PK13

Piercing Point  
1/2 Circle

**RESOLUT  
SUTURE NEEDLES**

Reverse Cutting  
3/8 Circle

PR-3  
RSPRE345  
PR-2  
R6PRE245  
PR-2  
RSPR245  
TT-7  
RUTE145

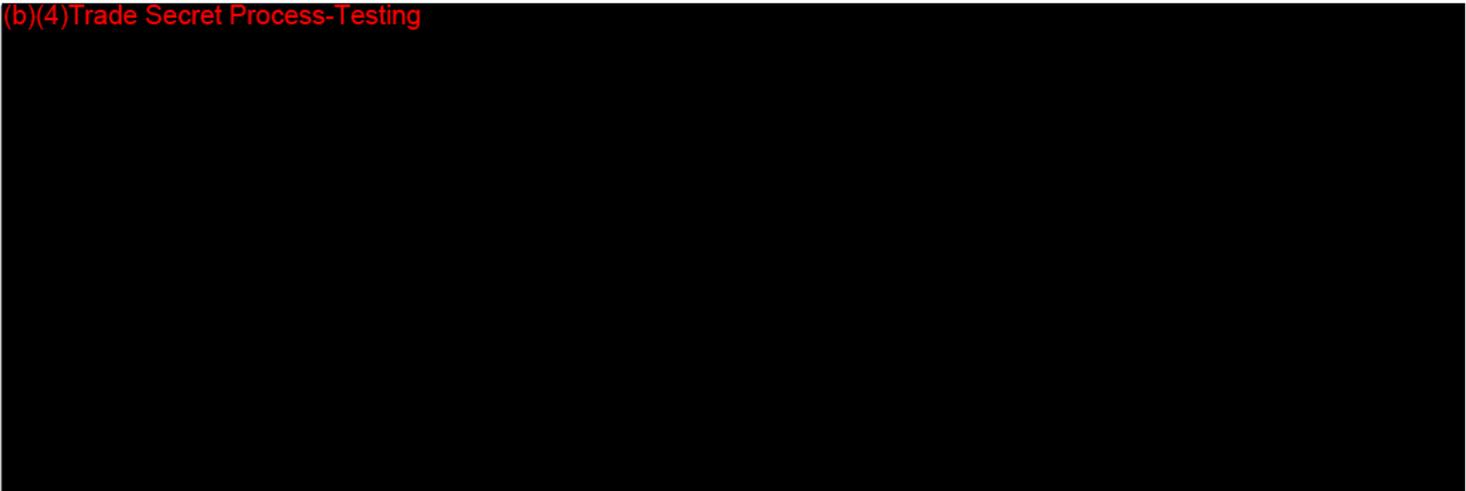
Taper Point  
3/8 Circle

Trademarks of W.L. Gore & Associates

# SECTION 6: BIOCOMPATIBILITY ASSESSMENT

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(b)(4) Trade Secret Process-Testing





## SECTION 7: STERILIZATION INFORMATION

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Cytoplast™ Sutures will be sterilized by (b)(4) [REDACTED] e [REDACTED] [REDACTED] [REDACTED] [REDACTED]. The sterilization process will be validated in accordance with current AMSI/AAMI/ISO guideline 11134-1993 and will provide a minimum Sterility Assurance Level (SAL) of  $1 \times 10^{-6}$ .