

2011033 1/1



99 Hayden Avenue
Suite 360
Lexington, MA 02421
tel: (781) 357-1700
fax: (781) 357-1701

Section X
Summary of Safety and Effectiveness

AUG 07 2009

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Tepha, Inc. is submitting the following summary of information respecting safety and effectiveness:

- Trade Name:** TephaFLEX® Surgical Film
- Sponsor:** Tepha, Inc.
99 Hayden Avenue, Suite 360
Lexington, MA 02421
Telephone: 781.357.1700
Fax: 781.357.1701
- Device Classification Name:** CFR §878.3300
Surgical Mesh
- Classification:** According to Section 13 of the Federal Food, Drug and Cosmetic Act, the device classification is Class II, Performance Standards.
- Predicate Devices:** Tepha, Inc. – TephaFLEX Surgical Film
Tepha, Inc. - TephaFLEX Absorbable Mesh
MAST Biosurgery, Inc. – Surgi-Wrap Film
OsteoBiologics – Immix PlastiFilm
- Device Description:** TephaFLEX surgical film is intended to be used wherever temporary wound support is required, to reinforce soft tissues where weakness exists in the urological, gynecological, or gastrointestinal anatomy, or for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. The absorbable protective film also may help minimize the potential for tissue attachment to the device in case of direct contact with the viscera.
- Safety and Performance:** Physical and *in vivo* animal testing was performed on the TephaFLEX surgical film which determined the film to be substantially equivalent to the predicate devices.
- Conclusion:** Based on the indications for use, technological characteristics, and safety and performance testing, the TephaFLEX surgical film has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Tepha, Inc
% Ms. Mary P. LeGrew
Vice President, Regulatory Affairs
99 Hayden Avenue, Suite 300
Lexington, Massachusetts 02421

AUG 07 2009

Re: K091633

Trade/Device Name: TephFLEX[®] Surgical Film
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OOD
Dated: June 3, 2009
Received: June 4, 2009

Dear Ms. LeGrew:

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 additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

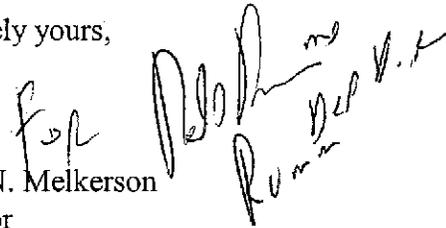
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Mary P. LeGrew

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', with some additional scribbles and initials to the right.

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

Enclosure

K091633

Indications for Use

510(k) Number (if known): Unknown

Device Name: TephaFLEX® Surgical Film

Indications for Use:

TephaFLEX® Surgical Film is intended to be used wherever temporary wound support is required, to reinforce soft tissues where weakness exists in the urological, gynecological, or gastrointestinal anatomy, or for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. The absorbable protective film also may help minimize the potential for tissue attachment to the device in case of direct contact with the viscera.

Prescription Use: X
(21 CFR 801 Subpart D)

AND/OR

Over-The-Counter ____
(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)

Page 1 of 1

David Krone for MxM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091633

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99 Hayden Avenue
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Lexington, MA 02421
tel: (781) 357-1700
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Section X
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(Prepared June 22, 2012)

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Sponsor: Tepha, Inc.
99 Hayden Avenue, Suite 360
Lexington, MA 02421
Telephone: 781.357.1700
Fax: 781.357.1701

Contact Person: Mary P. LeGraw, V.P., Regulatory Affairs

Device Classification Name: CFR §878.3300 – OOD, PAJ
Surgical Mesh

Classification: According to Section 13 of the Federal Food, Drug and Cosmetic Act, the device classification is Class II, Performance Standards.

Predicate Devices: Tepha, Inc. – TephaFLEX Surgical Film
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MAST Biosurgery, Inc. – Surgi-Wrap Film

Device Description: TephaFLEX surgical film is intended to be used wherever temporary wound support is required, to reinforce soft tissues where weakness exists in the urological, gynecological, or gastrointestinal anatomy, or for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. The absorbable protective film also may help minimize the potential for tissue attachment to the device in case of direct contact with the viscera.

Note: The TephaFLEX surgical mesh is not intended to be placed transvaginally. The film should be placed abdominally when being used to reinforce soft tissues in the urological, gynecological or gastrointestinal anatomy.

Safety and Performance: Mechanical testing, *in vivo* animal testing, and biocompatibility testing, were performed based on recommendations identified in the FDA surgical mesh guidance document: The Guidance for the Preparation of a Pre-market Notification Application for a Surgical Mesh. Specifically, comparative burst strength, suture pull-out strength, tensile strength and tear resistance strength was characterized. *In vivo* strength retention was characterized via a subcutaneous implantation study.

Conclusion: Based on the indications for use, technological characteristics, and safety and performance testing, the TephaFLEX surgical film has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.



Tepha, Incorporated
% Ms. Mary P. LeGrew
Vice President, Regulatory Affairs
99 Hayden Avenue, Suite 300
Lexington, Massachusetts 02421

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

AUG 24 2012

Re: K091633
Trade/Device Name: TephaFLEX[®] Surgical Film
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: OOD, PAJ
Dated: June 3, 2009
Received: June 4, 2009

Dear Ms. LeGrew:

This letter corrects our substantially equivalent letter of August 7, 2009.

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 (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.

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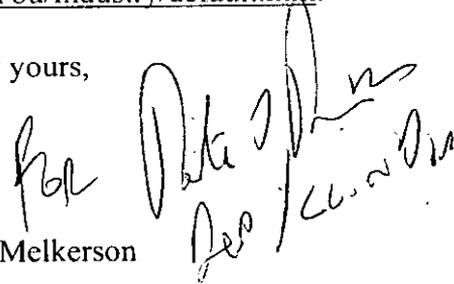
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Page 2 - Mary P. LeGrew

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Sincerely yours,

A handwritten signature in black ink, appearing to read 'for Mark N. Melkerson', is written over a circular stamp. The stamp contains the text 'CDRH' and 'Sep 16 2015'.

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

Enclosure

Page 3 - Mary P. LeGrew

Div/Branch	Last Name	Date	Div/Branch	Last Name	Date
ISO/O/PRSD	Kjune	8/24/09			
		8/24/09			

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table

Indications for Use

510(k) Number (if known): K091633

Device Name: TephaFLEX® Surgical Film

Indications for Use:

TephaFLEX® Surgical Film is intended to be used wherever temporary wound support is required, to reinforce soft tissues where weakness exists in the urological, gynecological, or gastrointestinal anatomy, or for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. The absorbable protective film also may help minimize the potential for tissue attachment to the device in case of direct contact with the viscera.

NOTE: The TephaFLEX Surgical Film is not intended to be placed transvaginally. The film should be placed abdominally when being used to reinforce soft tissues in the urological, gynecological or gastrointestinal anatomy.

Prescription Use: X
(21 CFR 801 Subpart D)

AND/OR

Over-The-Counter ____
(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)

Page 1 of 1

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091633

*Due
8/14/2012*

ATTENTION: EDWENA JONES

Date: 6/27/2012
Document: K091633/A001
Comments: please re-route 522 order to DSORD

Summary			
Document #:	K091633/A001	POS Status:	Under Review
Division:	DRGUD	Div. Status:	Under Review
Branch:	OGDB	Workflow:	Requires Recommendation
Product Code(s):	OOD, PAJ	FDA Due Date:	08/14/2012
Med. Specialty:	OB	FDA Days:	
		Mfr. Days:	
		Final Decision:	
		Decision Date:	
Applicant:	Tepha, Inc.		
Trade Name:	Tephaflex surgical film		
Common Name:	Absorbable poly(hydroxybutyrate) surgical film		
Additional Details			
Recommendation			
Lead Reviewer:	Edwena Jones		
Recommendation:			
Branch Due Date:	08/07/2012		
Branch Concur With Recommendation:	<input type="checkbox"/>		
Division Concur With Recommendation:	<input type="checkbox"/>		
Consults (0)			
Interactive Review Log (0)			
Linked EIR Reviews (0)			
Comments			
Date	User	Comment	
06/20/2012	David Krause	I received this file today (6/20). I noticed that it was intended for Becky Robinson in DRGUD. I have initiated transfer processes.	
06/25/2012	Rebecca Robinson	Revised indications for use statement acceptable. Since the device is primarily used and marketed for non-urogynecologic procedures, DSORD/PRSB is responsible for lead review and therefore should issue the corrected SE letter. This add-to-file will be transferred to them so that the letter may be issued.	

OK 7/10

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration

Memorandum

Date: 6/15

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K091033/A1

To: Division Director: ~~SO/ISSORD~~ ~~OB/ORBUD~~ DSORD

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

_____ Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

_____ Additional information requires a new 510(k); however, the information submitted is incomplete; (Notify company to submit a new 510(k); [Prepare the K30 Letter on the LAN]

_____ No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440)

_____ Information requires a CLIA CATEGORIZATION; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

_____ Additional information requires a CLIA CATEGORIZATION; however, the information submitted is incomplete; (call or fax firm)

_____ No response necessary

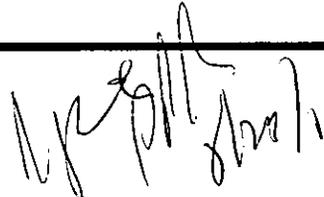
This information should be returned to the DMC within 10 working days from the date of this Memorandum.

Reviewed by: _____

Date: _____

Mackey, Cheryl

m: Robinson, Rebecca (Becky)
sent: Monday, June 25, 2012 9:37 AM
To: Krause, David; Jones, Edwena
Cc: Mackey, Cheryl; Andrews, Sharon M
Subject: K091633/A001 TephaFLEX Surgical Film (Tepha) - Corrected SE Letter (per 522 order)



Hi David,

The above referenced 510(k) add-to-file was submitted in response to a 522 order. The sponsor has removed all references to transvaginal repair of POP from their indications for use statement and has submitted a revised Indications for Use form, 510(k) Summary, and labeling accordingly. The sponsor also updated the 510(k) Summary to include an additional product code for sacrocolpopexy. I included a short memo documenting the 522 review history and my interactions with the sponsor with the add-to-file.

Because the Indications for Use statement no longer includes urogynecologic indications, we are transferring this add-to-file to your branch to issue the corrected SE letter.

Edwena – After you have received and date-stamped the corrected SE letter, would you please send Cheryl Mackey, Sharon, Andrews, and me an electronic copy of the final letter and indications for use form so we can provide OSB with a copy; the letter is needed to close out the 522 study order associated with this 510(k) submission.

Thanks,
ky



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

Revised Indications for Use Statement Review

K091633/A001

Date: June 22, 2012
From: Becky Robinson, Biomedical Engineer (ODE/DRGUD/OGDB) *BR 06-25-2012*
Subject: **Revised Indications for Use and labeling in response to 522 order PS120107**
Through: Elaine Blyskun, Chief (ODE/DRGUD/OGDB) *MTB for EMB 6/25/12*
To: The Record
Cc: Mary Beth Ritchey, Associate Director for Postmarket Surveillance Studies (OSB/DEPI)

510(k) Holder: Tepha, Inc.
Device Name: TephaFLEX® Surgical Film
Contact: Mary P. LeGraw, Vice President, Regulatory Affairs
Address: 99 Hayden Avenue, Suite 360, Lexington, MA 02421
Phone: (781) 357-1700
Fax: (781) 357-1701
Email: legraw@tepha.com

Purpose

The purpose of this review is to review the revised Indications for Use submitted by the sponsor in response to the letter sent to the sponsor on 04/09/2012 for the 522 study order PS120107.

Background

FDA issued Tepha two 522 orders for their TephaFLEX mesh/film devices (K070894 and K091633). In response to the 522 orders for these devices the sponsor indicated these 510(k)s are not marketed for use in transvaginal procedures. 522 staff sent an e-mail to the sponsor on 06/08/2012 requesting that they modify the indications for use statement "to remove any references to transvaginal repair of pelvic organ prolapse." This add-to-file includes the revised indications statement, 510(k) Summary, and labeling.

Device Description

The TephaFLEX Surgical Film is an absorbable mesh made of (b)(4) (b). This device is a flat, solid sheet, available in sizes ranging from 25 x 25 mm to 300 x 300 mm, and is not pre-configured or supplied with instrumentation specific to transvaginal POP repair. It was originally cleared on 08/07/2009 by DSORD/PRSB.

Revisions to Indications for Use Statements

Cleared Indications for Use statement:

*TephaFLEX® Surgical Film is intended to be used wherever temporary wound support is required, to reinforce soft tissues where weakness exists in the urological, **gynecological**, or gastrointestinal anatomy, or for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. The absorbable protective film also may help minimize the potential for tissue attachment to the device in case of direct contact with the viscera.*

The sponsor provided the following revised Indications for Use statement:

TephaFLEX® Surgical Film is intended to be used wherever temporary wound support is required, to reinforce soft tissues where weakness exists in the urological, gynecological, or gastrointestinal anatomy, or for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. The absorbable protective film also may help minimize the potential for tissue attachment to the device in case of direct contact with the viscera.

NOTE: *The TephaFLEX Surgical Film is not intended to be placed transvaginally. The film should be placed abdominally when being used to reinforce soft tissues in the urological, gynecological or gastrointestinal anatomy.*

The revised Indications for Use statement is adequate. The sponsor also provided a revised 510(k) Summary and labeling that included the new statement and new product codes (OOD and PAJ).

Recommendation

I recommend the sponsor be sent a corrected SE letter for the revised Indications for Use statement and 510(k) Summary. In addition, since the revised statement excludes transvaginal placement of mesh for repair of POP, I recommend the 522 order be terminated upon issuance of the corrected SE letter.

Since the device is primarily used and marketed for non-urogynecologic procedures, DSORD/PRSB is responsible for lead review and therefore should issue the corrected SE letter. This add-to-file will be transferred to them so that the letter may be issued and the 522 order terminated.

Robinson, Rebecca (Becky)

m: Mary P. LeGraw <legraw@tepha.com>
Sent: Friday, June 22, 2012 11:11 AM
To: Robinson, Rebecca (Becky)
Subject: RE: K091633/A001 TephafLEX Surgical Film 9Tepha) - Revised 510(k) Summary
Attachments: Revised Summary of Safety and Effectiveness.doc

Hi Becky

I have attached the revised summary; please let me know if there is anything else you need.

Best,
Mary

From: Robinson, Rebecca (Becky) [<mailto:Rebecca.Robinson@fda.hhs.gov>]
Sent: Friday, June 22, 2012 10:59 AM
To: 'Mary P. LeGraw'
Subject: RE: K091633/A001 TephafLEX Surgical Film 9Tepha) - Revised 510(k) Summary

Hi Mary,

I'm sorry you were not able to locate the PAJ product code. It is listed on the FDA public website under the 878.3300 regulation

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?start_search=1&Submission_Type_ID=&DeviceName=&ProductCode=&DeviceClass=&ThirdParty=&Panel=&RegulationNumber=878%2E3300&PAGENUM=50)
along with the other new product codes for this regulation.

Here is the direct link for the PAJ product code:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=3625>

Please let me know if you have trouble with the links.

Thanks,
Becky

Becky Robinson, PhD | Biomedical Engineer
Center for Devices and Radiological Health | Office of Device Evaluation | DRGUD/OGDB
U.S. Food and Drug Administration
10903 New Hampshire Avenue | Bldg. 66, Room G115 | Silver Spring, MD 20993

TEL: 301-796-6532 | FAX: 301-847-8111 | rebecca.robinson@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 e-mail or telephone.

From: Mary P. LeGraw [<mailto:legraw@tepha.com>]
Sent: Friday, June 22, 2012 10:31 AM
To: Robinson, Rebecca (Becky)
Subject: RE: K091633/A001 TephafLEX Surgical Film 9Tepha) - Revised 510(k) Summary

Dear Becky,

One question...what is the PAJ product code. I looked on the FDA database and it states there is no such code. I assume this is new, but can you explain what it is?

Thank you,
Mary

From: Robinson, Rebecca (Becky) [<mailto:Rebecca.Robinson@fda.hhs.gov>]
Sent: Friday, June 22, 2012 9:43 AM
To: 'legraw@tepha.com'
Subject: K091633/A001 TephafLEX Surgical Film 9Tepha) - Revised 510(k) Summary

Dear Ms. LeGraw,

I have reviewed your revised indications for use statement for the subject device. The statement as you have revised it is acceptable, however, before the corrected SE letter can be issued we will need a **revised 510(k) Summary that replaces the existing product code (OOD) with the OOD and PAJ product codes (in that order)**. Please e-mail the requested document to me—you do not need to send a copy to the Document Mail Center, as I will add a copy to the Record.

Please contact me if you have any questions.

Regards,

Becky Robinson, PhD | Biomedical Engineer
Center for Devices and Radiological Health | Office of Device Evaluation | DRGUD/OGDB
U.S. Food and Drug Administration
10903 New Hampshire Avenue | Bldg. 66, Room G115 | Silver Spring, MD 20993
TEL: 301-796-6532 | FAX: 301-847-8111 | rebecca.robinson@fda.hhs.gov

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Conclusion: Based on the indications for use, technological characteristics, and safety and performance testing, the TephaFLEX surgical film has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

Add-to-the-File

TephaFLEX® Surgical Film K091633 / A002

RE: (b) (4) Study (b) (4)

June 14, 2012

K091633/A1



99 Hayden Avenue
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tel: (781) 357-1700
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June 14, 2012

FDA CDRH DMC

JUN 15 2012

Received K43

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Bldg. 66, Room G115
Silver Spring, MD 20993-0002

RE: Add-to-the-File Submission for the TephafLEX Surgical Film – 510(k) Number K091633 / A001 / Post Market Surveillance (PS) Study: PS120107

Dear Sir/Madam:

Tepha is submitting this second Add to File to 510(k) K091633 / A002 / Post Market Surveillance Study: PS120107 in response to an e-mail communication we received on Tuesday, June 12th, from Dr. Becky Robinson regarding the original document that was submitted on June 11th.

Tepha received an e-mail notification from Dr. Robinson on Tuesday, June 12th regarding Tepha's Add to File which stated the following:

(b)(4) Testing

In response to Dr. Robinson's e-mail, Tepha suggested that the following additional language be added to the Indications for Use statement:

Note: The TephafLEX surgical film is not intended to be placed transvaginally. The film should be placed abdominally when being used to reinforce soft tissues in the urological, gynecological or gastrointestinal anatomy.

Dr. Robinson responded to Tepha's e-mail that the language Tepha suggested is appropriate and adequate to mitigate the risk of a physician using the device for transvaginal repair of POP. In a follow up telephone conversation, she suggested that Tepha submit another Add to File to CDRH that includes a revised Indications for Use form, 510(k) Summary, and labeling with the revised indications statement.

The revised documents are included in this Add to File, along with a copy of the e-mail communication between Tepha and Dr. Robinson.



99 Hayden Avenue
Suite 360
Lexington, MA 02421
tel: (781) 357-1700
fax: (781) 357-1701

It is my understanding that upon receipt of this notification, the 522 order will remain on hold until the FDA issues a corrected substantial equivalence letter with the revised Indications for Use statement for the TephaFLEX surgical film device.

This Notification is being submitted in triplicate. Should you have any questions or require additional information, please contact me directly at the contact information below.

Sincerely yours,

A handwritten signature in cursive script that reads "Mary P. LeGraw".

Mary P. LeGraw
Vice President, Regulatory Affairs
Tepha, Inc.
99 Hayden Avenue
Lexington, MA 02421
Telephone: 781.357.1709
Fax: 781.357.1701
Cell: 617.820.0387
e-Mail: legraw@tepha.com



99 Hayden Avenue
Suite 360
Lexington, MA 02421
tel: (781) 357-1700
fax: (781) 357-1701

Section X
Summary of Safety and Effectiveness
(Prepared June 14, 2012)

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Tepha, Inc. is submitting the following summary of information respecting safety and effectiveness:

Trade Name: TephaFLEX® Surgical Film

Sponsor: Tepha, Inc.
99 Hayden Avenue, Suite 360
Lexington, MA 02421
Telephone: 781.357.1700
Fax: 781.357.1701

Contact Person: Mary P. LeGraw, V.P., Regulatory Affairs

Device Classification Name: CFR §878.3300 - OOD
Surgical Mesh

Classification: According to Section 13 of the Federal Food, Drug and Cosmetic Act, the device classification is Class II, Performance Standards.

Predicate Devices: Tepha, Inc. – TephaFLEX Surgical Film
Tepha, Inc. - TephaFLEX Absorbable Mesh
MAST Biosurgery, Inc. – Surgi-Wrap Film

Device Description: TephaFLEX surgical film is intended to be used wherever temporary wound support is required, to reinforce soft tissues where weakness exists in the urological, gynecological, or gastrointestinal anatomy, or for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. The absorbable protective film also may help minimize the potential for tissue attachment to the device in case of direct contact with the viscera.

Note: The TephaFLEX surgical mesh is not intended to be placed transvaginally. The film should be placed abdominally when being used to reinforce soft tissues in the urological, gynecological or gastrointestinal anatomy.

Safety and Performance: Mechanical testing, *in vivo* animal testing, and biocompatibility testing, were performed based on recommendations identified in the FDA surgical mesh guidance document: The Guidance for the Preparation of a Pre-market Notification Application for a Surgical Mesh. Specifically, comparative burst strength, suture pull-out strength, tensile strength and tear resistance strength was characterized. *In vivo* strength retention was characterized via a subcutaneous implantation study.

Conclusion: Based on the indications for use, technological characteristics, and safety and performance testing, the TephaFLEX surgical film has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

Revised INSTRUCTIONS FOR USE
TephaFLEX® Surgical Film

DESCRIPTION

TephaFLEX surgical film is an absorbable film prepared from poly-4-hydroxybutyrate (P4HB). The film is available in solid sheets in sizes ranging from 25mm x 25mm to 300mm x 300mm. The thickness of the film is 60 to 200 microns and may be cut to the shape or size desired for a specific application.

INDICATIONS FOR USE

TephaFLEX Surgical Film is designed to be used wherever temporary wound support is required, to reinforce soft tissues where weakness exists in the urological, gynecological or gastroenterological anatomy, or for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. The absorbable protective film also may help minimize the potential for tissue attachment to the device in case of direct contact with the viscera.

NOTE: The TephaFLEX Surgical Film is not intended to be placed transvaginally. The film should be placed abdominally when being used to reinforce soft tissues in the urological, gynecological or gastrointestinal anatomy.

WARNINGS

TephaFLEX film is an absorbable product that will degrade over time. In repairs where permanent wound support is required, or if the repair requires a high degree of strength retention over a prolonged period of time, the film should be used in conjunction with an overlay patch to provide the long term mechanical strength required.

The safety and effectiveness of the TepahFLEX Absorbable Film used to reduce the incidence, extent and severity of postoperative adhesions have not been established in prospective, randomized clinical trials.

Device manufacture involves exposure to tetracycline hydrochloride and kanamycin sulfate. The safety and product use for patients with hypersensitivities to these antibiotics is unknown.

PRECAUTIONS

User should be familiar with surgical procedures and techniques, including strength requirements and film size and thickness choices. Improper size selection, placement, positioning, and fixation of the devices can cause subsequent undesirable results. The surgeon is to be familiar with the devices and the surgical procedure prior to performing surgery.

ACTIONS

TephaFLEX surgical film degrades through a process of hydrolysis and hydrolytic enzymatic degradation. It has been developed to minimize the variability of absorption rate (loss of mass) and strength retention, and provide wound support throughout the expected period of healing.

Subcutaneous implantation studies performed in a rabbit model indicate the following strength retention over time:

<i>In Vivo Mechanical Properties* - Burst Strength</i>				
Implantation Time Point	60 micron TephaFLEX Film	% Strength Retention	200 micron TephaFLEX Film	% Strength Retention
Time 0	11.46	100	20.93	100
3 Weeks	3.27	29	17.01	81
6 Weeks	1.97	17	8.06	39

* Full degradation is essentially complete within 12-15 months

STERILITY

TephaFLEX surgical film is sterilized by ethylene oxide gas (EO). Product is sterile unless package has been opened or damaged. **DO NOT RESTERILIZE.** Discard opened or unused containers.

DIRECTIONS FOR USE

The TephaFLEX film may be cut to the shape or size desired for each specific application. Some surgeons prefer to suture a piece larger than the defect into position over the defect. The device should be sutured in place around its perimeter to assure proper positioning and to prevent film migration or folding. Suturing should be performed in such manner leaving at least ¼ inch of material between the location of the passage of each stitch through the device and the closest portion of the edge.

STORAGE: Store in a cool, dry place.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Mary P. LeGraw

From: Robinson, Rebecca (Becky) [Rebecca.Robinson@fda.hhs.gov]
nt: Wednesday, June 13, 2012 1:30 PM
o: 'Mary P. LeGraw'
Subject: RE: K091633/A001 TephaFLEX Surgical Film - Revised Indications Statement

Hi Mary,

The language you have suggested, "**The TephaFLEX surgical film is not intended to be placed transvaginally. The film should be placed abdominally when being used to reinforce soft tissues in the urological, gynecological or gastrointestinal anatomy.**" is appropriate and adequate to mitigate the risk of a physician using the device for transvaginal repair of POP. Please submit a revised Indications for Use form, 510(k) Summary, and labeling with the revised indications statement that includes the additional language.

If you have any questions please e-mail or call me.

Thanks!
Becky

Becky Robinson, PhD | Biomedical Engineer
Center for Devices and Radiological Health | Office of Device Evaluation | DRGUD/OGDB
U.S. Food and Drug Administration
10903 New Hampshire Avenue | Bldg. 66, Room G115 | Silver Spring, MD 20993

TEL: 301-796-6532 | FAX: 301-847-8111 | rebecca.robinson@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 e-mail or telephone.

From: Mary P. LeGraw [mailto:legraw@tepha.com]
Sent: Tuesday, June 12, 2012 2:10 PM
To: Robinson, Rebecca (Becky)
Subject: RE: K091633/A001 TephaFLEX Surgical Film - Revised Indications Statement

Dear Becky,

When I originally spoke with Dr. Ritchey about the 522 order for our surgical mesh, she explained that the order is limited to manufacturer's who are commercializing surgical mesh for organ prolapse indications where the mesh is placed transvaginally. She stated that devices that are placed abdominally are not within the scope of the 522 order. Will it be adequate to revise the language in the NOTE to state, "The TephaFLEX surgical film is not intended to be placed transvaginally. The film should be placed abdominally when being used to reinforce soft tissues in the urological, gynecological or gastrointestinal anatomy?"

Since specific organ prolapse indications, such as colon prolapse, were not part of the original indication statement, I'm not clear on what additional language I should include. Please let me know if this language is satisfactory.

Best regards,
Mary

From: Robinson, Rebecca (Becky) [<mailto:Rebecca.Robinson@fda.hhs.gov>]
Sent: Tuesday, June 12, 2012 1:38 PM
To: Mary P. LeGraw (legraw@tepha.com)
Subject: K091633/A001 Tephaflex Surgical Film - Revised Indications Statement

Dear Ms. LeGraw,

I received the three additional copies of the add-to-file for K091633 sent to the FDA in response to the letter from Dr. Danica Marinac-Dabic on 06/08/2012. On page 2 of this letter the following comment was included:

In response to the 522 order issued on April 09, 2012 you provided a revised Indications for Use statement to clarify that the Tephaflex

(b)(4)

(b)(4), which is needed to determine the adequacy of your revised indications for use statement. Please provide a response to this comment to me via e-mail by Friday, June 29, 2012. I will add this response to the add-to-file so that it may be included in the official record.

If you have any questions please do not hesitate to contact me.

Regards,

Becky Robinson, PhD | Biomedical Engineer
Center for Devices and Radiological Health | Office of Device Evaluation | DRGUD/OGDB
U.S. Food and Drug Administration
10903 New Hampshire Avenue | Bldg. 66, Room G115 | Silver Spring, MD 20993
TEL: 301-796-6532 | FAX: 301-847-8111 | rebecca.robinson@fda.hhs.gov

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June 14, 2012

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Bldg. 66, Room G115
Silver Spring, MD 20993-0002

**RE: Add-to-the-File Submission for the TephaFLEX Surgical Film – 510(k) Number
K091633 / A001 / Post Market Surveillance (PS) Study: PS120107**

Dear Sir/Madam:

Tepha is submitting this second Add to File to 510(k) K091633 / A002 / Post Market Surveillance Study: PS120107 in response to an e-mail communication we received on Tuesday, June 12th, from Dr. Becky Robinson regarding the original document that was submitted on June 11th.

Tepha received an e-mail notification from Dr. Robinson on Tuesday, June 12th regarding Tepha's Add to File which stated the following:

(b)(4)

A large black rectangular redaction box covers the central portion of the document, obscuring the text that would follow the "the following:" statement. The redaction is labeled with "(b)(4)" in red text at the top left corner.

In response to Dr. Robinson's e-mail, Tepha suggested that the following additional language be added to the Indications for Use statement:

Note: The TephaFLEX surgical film is not intended to be placed transvaginally. The film should be placed abdominally when being used to reinforce soft tissues in the urological, gynecological or gastrointestinal anatomy.

Dr. Robinson responded to Tepha's e-mail that the language Tepha suggested is appropriate and adequate to mitigate the risk of a physician using the device for transvaginal repair of POP. In a follow up telephone conversation, she suggested that Tepha submit another Add to File to CDRH that includes a revised Indications for Use form, 510(k) Summary, and labeling with the revised indications statement.

The revised documents are included in this Add to File, along with a copy of the e-mail communication between Tepha and Dr. Robinson.



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tel: (781) 357-1700
fax: (781) 357-1701

It is my understanding that upon receipt of this notification, the 522 order will remain on hold until the FDA issues a corrected substantial equivalence letter with the revised Indications for Use statement for the TephaFLEX surgical film device.

This Notification is being submitted in triplicate. Should you have any questions or require additional information, please contact me directly at the contact information below.

Sincerely yours,

A handwritten signature in cursive script that reads "Mary P. LeGraw".

Mary P. LeGraw
Vice President, Regulatory Affairs
Tepha, Inc.
99 Hayden Avenue
Lexington, MA 02421
Telephone: 781.357.1709
Fax: 781.357.1701
Cell: 617.820.0387
e-Mail: legraw@tepha.com

Indications for Use

510(k) Number (if known): K091633

Device Name: TephaFLEX® Surgical Film

Indications for Use:

TephaFLEX® Surgical Film is intended to be used wherever temporary wound support is required, to reinforce soft tissues where weakness exists in the urological, gynecological, or gastrointestinal anatomy, or for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. The absorbable protective film also may help minimize the potential for tissue attachment to the device in case of direct contact with the viscera.

NOTE: The TephaFLEX Surgical Film is not intended to be placed transvaginally. The film should be placed abdominally when being used to reinforce soft tissues in the urological, gynecological or gastrointestinal anatomy.

Prescription Use: X
(21 CFR 801 Subpart D)

AND/OR

Over-The-Counter ____
(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)

Page 1 of 1



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Section X
Summary of Safety and Effectiveness
(Prepared June 14, 2012)

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Tepha, Inc. is submitting the following summary of information respecting safety and effectiveness:

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Sponsor: Tepha, Inc.
99 Hayden Avenue, Suite 360
Lexington, MA 02421
Telephone: 781.357.1700
Fax: 781.357.1701

Contact Person: Mary P. LeGraw, V.P., Regulatory Affairs

Device Classification Name: CFR §878.3300 - OOD
Surgical Mesh

Classification: According to Section 13 of the Federal Food, Drug and Cosmetic Act, the device classification is Class II, Performance Standards.

Predicate Devices: Tepha, Inc. – TephaFLEX Surgical Film
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Device Description: TephaFLEX surgical film is intended to be used wherever temporary wound support is required, to reinforce soft tissues where weakness exists in the urological, gynecological, or gastrointestinal anatomy, or for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. The absorbable protective film also may help minimize the potential for tissue attachment to the device in case of direct contact with the viscera.

Note: The TephaFLEX surgical mesh is not intended to be placed transvaginally. The film should be placed abdominally when being used to reinforce soft tissues in the urological, gynecological or gastrointestinal anatomy.

Safety and Performance: Mechanical testing, *in vivo* animal testing, and biocompatibility testing, were performed based on recommendations identified in the FDA surgical mesh guidance document: The Guidance for the Preparation of a Pre-market Notification Application for a Surgical Mesh. Specifically, comparative burst strength, suture pull-out strength, tensile strength and tear resistance strength was characterized. *In vivo* strength retention was characterized via a subcutaneous implantation study.

Conclusion: Based on the indications for use, technological characteristics, and safety and performance testing, the TephaFLEX surgical film has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

Revised - INSTRUCTIONS FOR USE
TephaFLEX® Surgical Film

DESCRIPTION

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NOTE: The TephaFLEX Surgical Film is not intended to be placed transvaginally. The film should be placed abdominally when being used to reinforce soft tissues in the urological, gynecological or gastrointestinal anatomy.

WARNINGS

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ACTIONS

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Subcutaneous implantation studies performed in a rabbit model indicate the following strength retention over time:

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Implantation Time Point	60 micron TephaFLEX Film	% Strength Retention	200 micron TephaFLEX Film	% Strength Retention
Time 0	11.46	100	20.93	100
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* Full degradation is essentially complete within 12-15 months

STERILITY

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DIRECTIONS FOR USE

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STORAGE: Store in a cool, dry place.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Mary P. LeGraw

From: Robinson, Rebecca (Becky) [Rebecca.Robinson@fda.hhs.gov]
Int: Wednesday, June 13, 2012 1:30 PM
To: 'Mary P. LeGraw'
Subject: RE: K091633/A001 TephaFLEX Surgical Film - Revised Indications Statement

Hi Mary,

The language you have suggested, **“The TephaFLEX surgical film is not intended to be placed transvaginally. The film should be placed abdominally when being used to reinforce soft tissues in the urological, gynecological or gastrointestinal anatomy.”** is appropriate and adequate to mitigate the risk of a physician using the device for transvaginal repair of POP. Please submit a revised Indications for Use form, 510(k) Summary, and labeling with the revised indications statement that includes the additional language.

If you have any questions please e-mail or call me.

Thanks!
Becky

Becky Robinson, PhD | Biomedical Engineer
Center for Devices and Radiological Health | Office of Device Evaluation | DRGUD/OGDB
U.S. Food and Drug Administration
10903 New Hampshire Avenue | Bldg. 66, Room G115 | Silver Spring, MD 20993

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Best regards,
Mary

From: Robinson, Rebecca (Becky) [<mailto:Rebecca.Robinson@fda.hhs.gov>]
Sent: Tuesday, June 12, 2012 1:38 PM
To: Mary P. LeGraw (legraw@tepha.com)
Subject: K091633/A001 Tephaflex Surgical Film - Revised Indications Statement

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(b)(4)

(b)(4), which is needed to determine the adequacy of your revised indications for use statement. Please provide a response to this comment to me via e-mail by Friday, June 29, 2012. I will add this response to the add-to-file so that it may be included in the official record.

If you have any questions please do not hesitate to contact me.

Regards,

Becky Robinson, PhD | Biomedical Engineer
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June 14, 2012

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Bldg. 66, Room G115
Silver Spring, MD 20993-0002

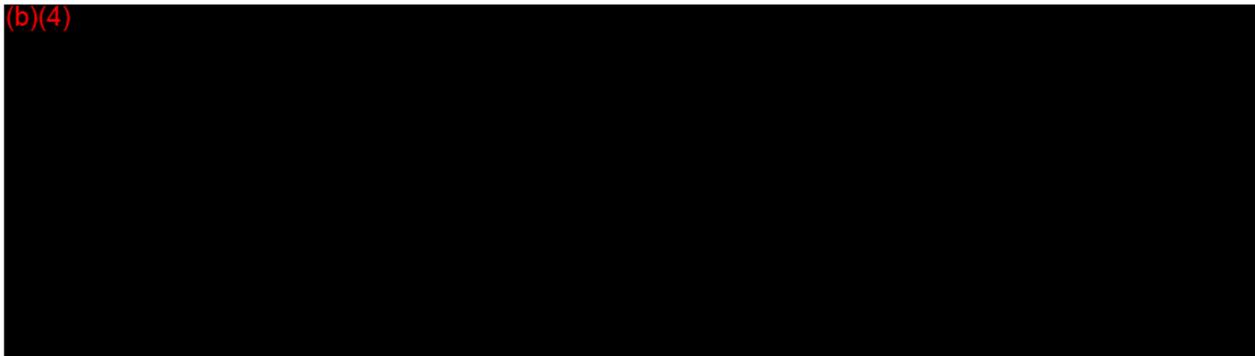
**RE: Add-to-the-File Submission for the TephaFLEX Surgical Film – 510(k) Number
K091633 / A001 / Post Market Surveillance (PS) Study: PS120107**

Dear Sir/Madam:

Tepha is submitting this second Add to File to 510(k) K091633 / A002 / Post Market Surveillance Study: PS120107 in response to an e-mail communication we received on Tuesday, June 12th, from Dr. Becky Robinson regarding the original document that was submitted on June 11th.

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(b)(4)

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In response to Dr. Robinson's e-mail, Tepha suggested that the following additional language be added to the Indications for Use statement:

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This Notification is being submitted in triplicate. Should you have any questions or require additional information, please contact me directly at the contact information below.

Sincerely yours,

A handwritten signature in cursive script that reads "Mary P. LeGraw".

Mary P. LeGraw
Vice President, Regulatory Affairs
Tepha, Inc.
99 Hayden Avenue
Lexington, MA 02421
Telephone: 781.357.1709
Fax: 781.357.1701
Cell: 617.820.0387
e-Mail: legraw@tepha.com

Indications for Use

510(k) Number (if known): K091633

Device Name: TephaFLEX® Surgical Film

Indications for Use:

TephaFLEX® Surgical Film is intended to be used wherever temporary wound support is required, to reinforce soft tissues where weakness exists in the urological, gynecological, or gastrointestinal anatomy, or for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. The absorbable protective film also may help minimize the potential for tissue attachment to the device in case of direct contact with the viscera.

NOTE: The TephaFLEX Surgical Film is not intended to be placed transvaginally. The film should be placed abdominally when being used to reinforce soft tissues in the urological, gynecological or gastrointestinal anatomy.

Prescription Use: X
(21 CFR 801 Subpart D)

AND/OR

Over-The-Counter ____
(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)

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Section X
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Trade Name: TephaFLEX® Surgical Film

Sponsor: Tepha, Inc.
99 Hayden Avenue, Suite 360
Lexington, MA 02421
Telephone: 781.357.1700
Fax: 781.357.1701

Contact Person: Mary P. LeGraw, V.P., Regulatory Affairs

Device Classification Name: CFR §878.3300 - OOD
Surgical Mesh

Classification: According to Section 13 of the Federal Food, Drug and Cosmetic Act, the device classification is Class II, Performance Standards.

Predicate Devices: Tepha, Inc. – TephaFLEX Surgical Film
Tepha, Inc. - TephaFLEX Absorbable Mesh
MAST Biosurgery, Inc. – Surgi-Wrap Film

Device Description: TephaFLEX surgical film is intended to be used wherever temporary wound support is required, to reinforce soft tissues where weakness exists in the urological, gynecological, or gastrointestinal anatomy, or for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. The absorbable protective film also may help minimize the potential for tissue attachment to the device in case of direct contact with the viscera.

Note: The TephaFLEX surgical mesh is not intended to be placed transvaginally. The film should be placed abdominally when being used to reinforce soft tissues in the urological, gynecological or gastrointestinal anatomy.

Safety and Performance: Mechanical testing, *in vivo* animal testing, and biocompatibility testing, were performed based on recommendations identified in the FDA surgical mesh guidance document: The Guidance for the Preparation of a Pre-market Notification Application for a Surgical Mesh. Specifically, comparative burst strength, suture pull-out strength, tensile strength and tear resistance strength was characterized. *In vivo* strength retention was characterized via a subcutaneous implantation study.

Conclusion: Based on the indications for use, technological characteristics, and safety and performance testing, the TephaFLEX surgical film has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

Revised - INSTRUCTIONS FOR USE
TephaFLEX® Surgical Film

DESCRIPTION

TephaFLEX surgical film is an absorbable film prepared from poly-4-hydroxybutyrate (P4HB). The film is available in solid sheets in sizes ranging from 25mm x 25mm to 300mm x 300mm. The thickness of the film is 60 to 200 microns and may be cut to the shape or size desired for a specific application.

INDICATIONS FOR USE

TephaFLEX Surgical Film is designed to be used wherever temporary wound support is required, to reinforce soft tissues where weakness exists in the urological, gynecological or gastroenterological anatomy, or for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. The absorbable protective film also may help minimize the potential for tissue attachment to the device in case of direct contact with the viscera.

NOTE: The TephaFLEX Surgical Film is not intended to be placed transvaginally. The film should be placed abdominally when being used to reinforce soft tissues in the urological, gynecological or gastrointestinal anatomy.

WARNINGS

TephaFLEX film is an absorbable product that will degrade over time. In repairs where permanent wound support is required, or if the repair requires a high degree of strength retention over a prolonged period of time, the film should be used in conjunction with an overlay patch to provide the long term mechanical strength required.

The safety and effectiveness of the TepahFLEX Absorbable Film used to reduce the incidence, extent and severity of postoperative adhesions have not been established in prospective, randomized clinical trials.

Device manufacture involves exposure to tetracycline hydrochloride and kanamycin sulfate. The safety and product use for patients with hypersensitivities to these antibiotics is unknown.

PRECAUTIONS

User should be familiar with surgical procedures and techniques, including strength requirements and film size and thickness choices. Improper size selection, placement, positioning, and fixation of the devices can cause subsequent undesirable results. The surgeon is to be familiar with the devices and the surgical procedure prior to performing surgery.

ACTIONS

TephaFLEX surgical film degrades through a process of hydrolysis and hydrolytic enzymatic degradation. It has been developed to minimize the variability of absorption rate (loss of mass) and strength retention, and provide wound support throughout the expected period of healing.

Subcutaneous implantation studies performed in a rabbit model indicate the following strength retention over time:

<i>In Vivo</i> Mechanical Properties* - Burst Strength				
Implantation Time Point	60 micron TephaFLEX Film	% Strength Retention	200 micron TephaFLEX Film	% Strength Retention
Time 0	11.46	100	20.93	100
3 Weeks	3.27	29	17.01	81
6 Weeks	1.97	17	8.06	39

* Full degradation is essentially complete within 12-15 months

STERILITY

TephaFLEX surgical film is sterilized by ethylene oxide gas (EO). Product is sterile unless package has been opened or damaged. **DO NOT RESTERILIZE.** Discard opened or unused containers.

DIRECTIONS FOR USE

The TephaFLEX film may be cut to the shape or size desired for each specific application. Some surgeons prefer to suture a piece larger than the defect into position over the defect. The device should be sutured in place around its perimeter to assure proper positioning and to prevent film migration or folding. Suturing should be performed in such manner leaving at least ¼ inch of material between the location of the passage of each stitch through the device and the closest portion of the edge.

STORAGE: Store in a cool, dry place.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Mary P. LeGraw

From: Robinson, Rebecca (Becky) [Rebecca.Robinson@fda.hhs.gov]
Sent: Wednesday, June 13, 2012 1:30 PM
To: 'Mary P. LeGraw'
Subject: RE: K091633/A001 TephaFLEX Surgical Film - Revised Indications Statement

Hi Mary,

The language you have suggested, "**The TephaFLEX surgical film is not intended to be placed transvaginally. The film should be placed abdominally when being used to reinforce soft tissues in the urological, gynecological or gastrointestinal anatomy.**" is appropriate and adequate to mitigate the risk of a physician using the device for transvaginal repair of POP. Please submit a revised Indications for Use form, 510(k) Summary, and labeling with the revised indications statement that includes the additional language.

If you have any questions please e-mail or call me.

Thanks!
Becky

Becky Robinson, PhD | Biomedical Engineer
Center for Devices and Radiological Health | Office of Device Evaluation | DRGUD/OGDB
U.S. Food and Drug Administration
10903 New Hampshire Avenue | Bldg. 66, Room G115 | Silver Spring, MD 20993

TEL: 301-796-6532 | FAX: 301-847-8111 | rebecca.robinson@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 e-mail or telephone.

From: Mary P. LeGraw [mailto:legraw@tepha.com]
Sent: Tuesday, June 12, 2012 2:10 PM
To: Robinson, Rebecca (Becky)
Subject: RE: K091633/A001 TephaFLEX Surgical Film - Revised Indications Statement

Dear Becky,

When I originally spoke with Dr. Ritchey about the 522 order for our surgical mesh, she explained that the order is limited to manufacturer's who are commercializing surgical mesh for organ prolapse indications where the mesh is placed transvaginally. She stated that devices that are placed abdominally are not within the scope of the 522 order. Will it be adequate to revise the language in the NOTE to state, "The TephaFLEX surgical film is not intended to be placed transvaginally. The film should be placed abdominally when being used to reinforce soft tissues in the urological, gynecological or gastrointestinal anatomy?"

Since specific organ prolapse indications, such as colon prolapse, were not part of the original indication statement, I'm not clear on what additional language I should include. Please let me know if this language is satisfactory.

Best regards,
Mary

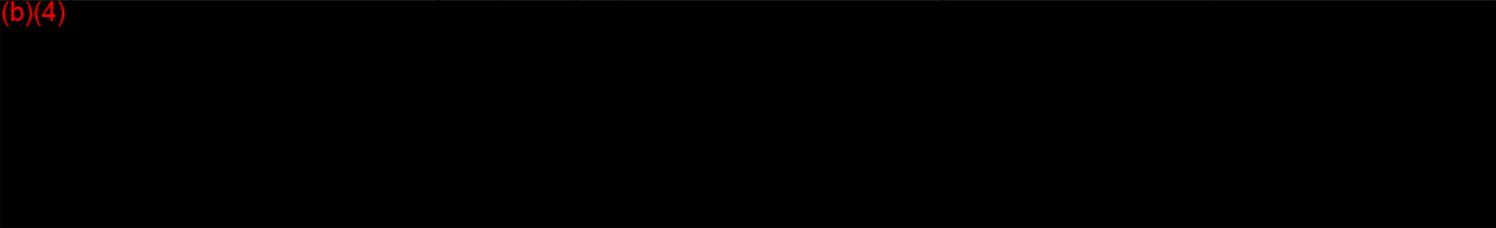
From: Robinson, Rebecca (Becky) [mailto:Rebecca.Robinson@fda.hhs.gov]
Sent: Tuesday, June 12, 2012 1:38 PM
To: Mary P. LeGraw (legraw@tepha.com)
Subject: K091633/A001 Tephaflex Surgical Film - Revised Indications Statement

Dear Ms. LeGraw,

I received the three additional copies of the add-to-file for K091633 sent to the FDA in response to the letter from Dr. Danica Marinac-Dabic on 06/08/2012. On page 2 of this letter the following comment was included:

In response to the 522 order issued on April 09, 2012 you provided a revised Indications for Use statement to clarify that the Tephaflex

(b)(4)



(b)(4), which is needed to determine the adequacy of your revised indications for use statement. Please provide a response to this comment to me via e-mail by Friday, June 29, 2012. I will add this response to the add-to-file so that it may be included in the official record.

If you have any questions please do not hesitate to contact me.

Regards,

Becky Robinson, PhD | Biomedical Engineer
Center for Devices and Radiological Health | Office of Device Evaluation | DRGUD/OGDB
U.S. Food and Drug Administration
303 New Hampshire Avenue | Bldg. 66, Room G115 | Silver Spring, MD 20993
TEL: 301-796-6532 | FAX: 301-847-8111 | rebecca.robinson@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 e-mail or telephone.



DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Tepha, Inc
% Ms. Mary P. LeGrew
Vice President, Regulatory Affairs
99 Hayden Avenue, Suite 300
Lexington, Massachusetts 02421

AUG 07 2009

Re: K091633

Trade/Device Name: TephFLEX[®] Surgical Film
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OOD
Dated: June 3, 2009
Received: June 4, 2009

Dear Ms. LeGrew:

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 additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

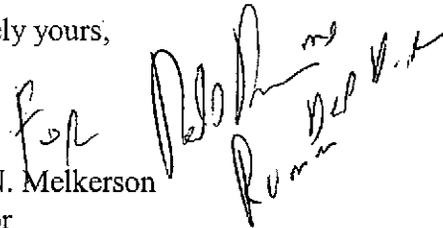
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Mary P. LeGrew

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "for Mark N. Melkerson". The signature is written in a cursive style and is positioned above the printed name and title.

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

Enclosure

DJA x00002



June 04, 2009

TEPHA, INC.
99 HAYDEN, SUTIE 360
LEXINGTON, MASSACHUSETTS 02421
UNITED STATES
ATTN: MARY P. LEGRAW

510k Number: K091633

Received: 6/4/2009

Product: TEPHAFLEX SURGICAL FILM

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.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/cdrh/mdufma/index.html> for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf>.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form (<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf>) accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Records processed under FOIA Request # 2015-6047; Released by CDRH on 11-30-2015
Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007”
(http://www.fda.gov/oc/initiatives/fdaaa/guidance_certifications.html). According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, “Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements”. This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1655.pdf>. Please refer to this guidance for information on a formalized interactive review process. 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).

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/electsub.html. In addition, the 510(k) Program Video is now available for viewing on line at www.fda.gov/cdrh/video/510k.wmv.

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
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

FDA CDRH DMC

JUN 4 2009

Received

K091633

510(K) Pre-market Notification

TephaFLEX® Surgical Film

June 3, 2009

54
#

K12

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DJA x00026

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SECTION I

GENERAL INFORMATION

NOTIFICATION LETTER

DJA 1000029



99 Hayden Avenue
Suite 360
Lexington, MA 02421
tel: (781) 357-1700
fax: (781) 357-1701

June 3, 2009

FDA/CDRH/DMC

JUN 4 2009

Received

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

RE: Pre-market Notification – Tephaflex® Surgical Film

Dear Sir/Madam:

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, and in conformance with 21 CFR §807, Tepha, Inc. submits this Pre-market Notification. Tepha intends to introduce into interstate commerce for commercial distribution the Tephaflex® Surgical Film intended to be used wherever temporary wound support is required, to reinforce soft tissues where weakness exists in the urological, gynecological or gastrointestinal anatomy, or for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. The absorbable protective film also may help minimize the potential for tissue attachment to the device in case of direct contact with the viscera.

Tephaflex film is manufactured from an absorbable material known as (b)(4) (b)(4) Test results are presented in the following pages.

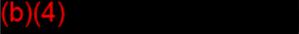
The following information is being submitted in conformance with 21 CFR §807.7:

- 1) **Classification Name:** Absorbable Poly-(hydroxybutyrate) Surgical Mesh
- 2) **Trade/Proprietary Name:** Tephaflex® Surgical Film
- 3) **Establishment Registration Number:** 3005670760
- 4) **Owner/Operator:** Tepha, Incorporated
99 Hayden Avenue, Suite 360
Lexington, MA 02421
Telephone: 781.357.1700
Fax: 781.357.1701
Owner/Operator Number: 10023049



99 Hayden Avenue
Suite 360
Lexington, MA 02421
tel: (781) 357-1700
fax: (781) 357-1701

- 5) **Company Contact:** Mary P. LeGraw
V.P., Regulatory Affairs
Tepha Medical Devices, Incorporated
Telephone: 781.357.1709
Fax: 781.357.1701
E-mail: legraw@Tepha.com
- 6) **Manufacturing Site:** Tepha, Inc.
99 Hayden Avenue
Lexington, MA 02421
Telephone: 781.357.1700
Fax: 781.357.1701
Establishment Registration: 3005670760
- 7) **Sterilization Site:** (b)(4) Third Party Information

- 8) **Packaging Site:** Tepha, Incorporated
99 Hayden Avenue
Lexington, MA 02421
Telephone: 781.357.1700
Fax: 781.357.1701
Establishment Registration: 3005670760
- 9) **Classification:** According to Section 513 of the Federal Food, Drug and Cosmetic Act, the device classification is Class II, Performance Standards.
- 10) **Device Panel:** General and Plastic Surgery
- 11) **Performance Standards:** Class II Special Controls Guidance Document: Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh. Class II Special Controls Guidance Document: Absorbable Poly(hydroxybutyrate) Surgical Suture Produced by Recombinant DNA Technology.
- 12) **Labeling:** A draft label and Instructions for Use are located in Section VIII.
- 13) **Confidentiality:** Tepha, Incorporated considers (b)(4)  s (b)(4)   to be confidential commercial information and exempt from public disclosure. Tepha understands that the data contained in this submission will be restricted from release under the Freedom of Information Act for at least 90 days or until concurrence is gained.



99 Hayden Avenue
Suite 360
Lexington, MA 02421
tel: (781) 357-1700
fax: (781) 357-1701

- 14) **Summary of Safety and Effectiveness:** A summary of the safety and effectiveness information contained with this Pre-market Notification is presented in Section X.

It is the understanding of Tepha that FDA does not presently require the submission of post marketing surveillance plans for this type of device, and that manufacturers will be notified when such requirements become applicable.

This Pre-market Notification is submitted in triplicate. Should you have any questions, please contact me directly at the contact information below.

Sincerely yours,

A handwritten signature in cursive script that reads "Mary P. LeGraw".

Mary P. LeGraw
Vice President, Regulatory Affairs
Tepha, Inc.
99 Hayden Avenue
Lexington, MA 02421
Telephone: 781.357.1709
Fax: 781.357.1701
Cell: 617.283.6539
E-Mail: legraw@tepha.com

MEDICAL DEVICE USER FEE COVER SHEET

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. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/cover sheet.html		
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) TEPHA INC 99 HAYDEN AVENUE SUITE 360 Lexington MA 02421 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)(4)	2. CONTACT NAME Mary LeGraw 2.1 E-MAIL ADDRESS legraw@tepha.com 2.2 TELEPHONE NUMBER (include Area code) 781-357-1709 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 781-357-1701	
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma) Select an application type:		
<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice	3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)	
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:		
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)		
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially		
7. 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). <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b)(4)		14-May-2009

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

7

INDICATIONS FOR USE STATEMENT

TRUTHFUL AND ACCURATE STATEMENT

TRUTHFUL AND ACCURATE STATEMENT

Pursuant to 21 CFR 807.87(k), I, Mary P. LeGraw, certify that to the best of my knowledge and belief and based upon the data and information submitted to me in the course of my responsibilities as Vice President of Regulatory Affairs, and reliance thereupon, the data and information submitted in the Pre-market Notification are truthful and accurate and that no facts material for a review of the substantial equivalence of this device have been knowingly omitted from this submission.

Mary P. LeGraw

Signature

Mary P. LeGraw

Printed Name

June 3, 2009

Date

N/A

510(k) Number

CDRH SUBMISSION COVER SHEET

CDRH SUBMISSION COVER SHEET

FDA CDRH DMC

Date of Submission:

FDA Document Number:

JUN 4 2009

DJA X00039

Section A		Type of Submission		
PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	PMA Supplement <input type="checkbox"/> Regular <input type="checkbox"/> Special <input type="checkbox"/> Panel Track <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 Supplement	PDP <input type="checkbox"/> Presubmission Summary <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of intent to start clinical trials <input type="checkbox"/> Intention to submit Notice of Completion <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP <input type="checkbox"/> Report	510(k) Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated <input type="checkbox"/> Additional Information: <input type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated <input type="checkbox"/> Report Amendment	Meeting <input type="checkbox"/> Pre-IDE mtg. <input type="checkbox"/> Pre-PMA mtg. <input type="checkbox"/> Pre-PDP mtg. <input type="checkbox"/> 180-Day mtg. <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption <input type="checkbox"/> Original submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report	Class II Exemption <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission Describe Submission:

Received

Section B		Applicant or Sponsor		
Company/Institution Name: Tepha Medical Devices, Inc.		Establishment registration number: 3005670760		
Division Name (if applicable):		Phone number (include area code): 781.357.1700		
Street Address: 99 Hayden Avenue, Suite 360		Fax number (include area code): 781.357.1701		
City: Lexington	State/Province: MA	Zip code: 02421	Country: USA	
Contact Name: Mary P. LeGraw: Direct: (781)357-1709				
Contact Title: Vice President, Regulatory Affairs			Contact e-mail address: legraw@tepha.com	

Section C		Submission Correspondent (if different from above)		
Company/Institution Name: N/A		Establishment registration number:		
Division name (if applicable)		Phone number (include area code):		
Street Address:		Fax number (include area code):		
City:	State/Province:	Zip Code:	Country: 13	
Contact Name: Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118				

DJA 200040

Section D1

Reason for Submission – PMA,PDP, or HDE

- | | | |
|--|---|--|
| <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"/> Material | <input type="checkbox"/> Packager |
| | <input type="checkbox"/> Specifications | <input type="checkbox"/> Distributor |
| | <input type="checkbox"/> Other (specify below) | |
| <input type="checkbox"/> Processing Change: | <input type="checkbox"/> Labeling Change: | <input type="checkbox"/> Report Submission: |
| <input type="checkbox"/> Manufacturing | <input type="checkbox"/> Indications | <input type="checkbox"/> Annual or Periodic |
| <input type="checkbox"/> Sterilization | <input type="checkbox"/> Instructions | <input type="checkbox"/> Post Approval Study |
| <input type="checkbox"/> Packaging | <input type="checkbox"/> Performance Characteristics | <input type="checkbox"/> Adverse Reaction |
| <input type="checkbox"/> Other (specify below) | <input type="checkbox"/> Shelf Life | <input type="checkbox"/> Device Defect |
| <input type="checkbox"/> Response to FDA correspondence: | <input type="checkbox"/> Trade Name | <input type="checkbox"/> Amendment |
| <input type="checkbox"/> Request for applicant hold | <input type="checkbox"/> Other (specify below) | |
| <input type="checkbox"/> Request for removal of applicant hold | | <input type="checkbox"/> Change in Ownership |
| <input type="checkbox"/> Request for extension | | <input type="checkbox"/> Change in correspondent |
| <input type="checkbox"/> Request to remove or add manufacturing site | | |
| <input type="checkbox"/> Other Reason (specify): | | |

Section D2

Reason for Submission - IDE

- | | | |
|--|--|---|
| <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 approval |
| <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 process | <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 for time to respond to FDA |
| <input type="checkbox"/> Unanticipated adverse effect | <input type="checkbox"/> Sponsor | <input type="checkbox"/> Request meeting |
| <input type="checkbox"/> Notification of emergency use | <input type="checkbox"/> Report Submission: | |
| <input type="checkbox"/> Compassionate use request | <input type="checkbox"/> Current investigator | |
| <input type="checkbox"/> Treatment IDE | <input type="checkbox"/> Annual progress | |
| <input type="checkbox"/> Continuing availability request | <input type="checkbox"/> Site waiver limit reached | |
| | <input type="checkbox"/> Final | |
| <input type="checkbox"/> Other reason (specify): | | |

Section D3

Reason for Submission – 510(k)

- | | | |
|---|---|--|
| <input checked="" type="checkbox"/> New Device | <input type="checkbox"/> Change in technology | <input type="checkbox"/> Change in materials |
| <input type="checkbox"/> Additional or expanded indications | <input type="checkbox"/> Change in design | <input type="checkbox"/> Change in manufacturing process |
| <input type="checkbox"/> Other reason (specify): | | |

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DJA 200041

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 data: <input checked="" type="checkbox"/> 510(k) summary attached <input type="checkbox"/> 510(k) statement
1	FTM	2	FTL	
3		4		
5		6		
7		8		

510(k) Number	Trade or Proprietary or model name	Manufacturer
1 K072520	TephaFLEX Surgical Film	Tepha, Incorporated
2 K070894	TephaFLEX Absorbable Mesh	Tepha, Incorporated
3 K050332	SurgiWrap	MAST Biosurgery, Inc.
4 K033671	Gore Bioabsorbable Mesh	W.L. Gore & Associates
5 K032673	Immix - PlastiFilm	OsteoBiologics, Inc.

Section F

Product Information – Applicable to All Applications

Common or usual name or classification name: Absorbable Poly(hydroxybutyrate) Surgical Film

Trade or proprietary or model name	Model Number
1 TephaFLEX® Surgical Film	1 N/A
2	2
3	3
4	4
5	5

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

1 K052225	2 K070894	3 K072520	4	5	6
7	8	9	10	11	12

Data included in submission: Laboratory Testing Animal Trials Human Trials

Section G

Product Classification – Applicable to All Applicants

Product code: FTL	C.F.R. Section 21 CFR §878.3300	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 and Plastic Surgery		(15)

Indications (from labeling): TephaFLEX® Surgical Film is intended to be used wherever temporary wound support is required, to reinforce soft tissues where weakness exists in urological, gynecological, or gastrointestinal anatomy, or for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. The absorbable protective film also may help minimize the potential for tissue attachment to the device in case of direct contact with the viscera.

DJA 200042

FDA Document Number:

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

Section H Manufacturing/Packaging/Sterilization Sites Relating to a Submission

<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
--	--	---



<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment registration number: TBD	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager/relabeler
--	---	---

Company/Institution Name: Tepha, Inc.		Establishment registration number: 3005670760	
Division name (if applicable):		Phone number (include area code): 781.357.1700	
Street address: 99 Hayden Avenue, Suite 360		FAX number (include area code): 781.357.1701	
City: Lexington	State/Province: MA	Zip code: 02421	Country: USA

Contact name: (b)(6)

Contact title: Sr. Director, Quality Systems	Contact e-mail address: (b)(6) (b)(4)
--	---------------------------------------

<input checked="" 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 (include area code):	
Street address:		FAX number (include area code):	
City:	State/Province:	Zip code:	Country:

Contact name:

Contact title:	Contact e-mail address:
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FDA FORM 3674

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Clinical data was not required or referred to in support of this 510(k) application; therefore, FDA Form 3674 is not included as part of this application.

DJA x00044

SECTION II

DEVICE DESCRIPTION

Section II Device Description

Device Description

The proposed film is an absorbable implant manufactured from (b)(4) (b) (b)(4) is a moldable, thermoplastic material that can be processed (b)(4) (b)(4). The manufacturing process for this film is (b)(4)

(b)(4) (b)(4) The material used in the manufacture of the proposed film is identical in terms of formulation and polymer manufacturing processes to the material used in the TephafLEX surgical film, cleared under K072520. The strength of TephafLEX film compares well with that of currently marketed film products as is supported by the data presented in support of this application.

The current TephafLEX surgical film was cleared by the FDA on November 29, 2007. The existing film is a solid sheet provided in sizes 50mm x 70mm, 100mm x 130mm, 130mm x 200mm, and is approximately 200 microns thick. The proposed film includes sizes ranging from 25mm x 25mm to 300mm x 300mm, as well as a thickness range of 60 through 200 microns. The length and width of the film will have no impact on the functional characteristics of the device. The addition of a thinner film may have an impact on the performance attributes of the product; therefore, testing was performed to confirm the strength requirements of the 60 micron film are substantially equivalent to the predicate devices that are cleared for the same clinical indications.

A photograph of the film product is provided at the end of this section. The design specifications for the proposed TephafLEX surgical film are outlined in Table 1 below.

**Table 1
Product Specifications**

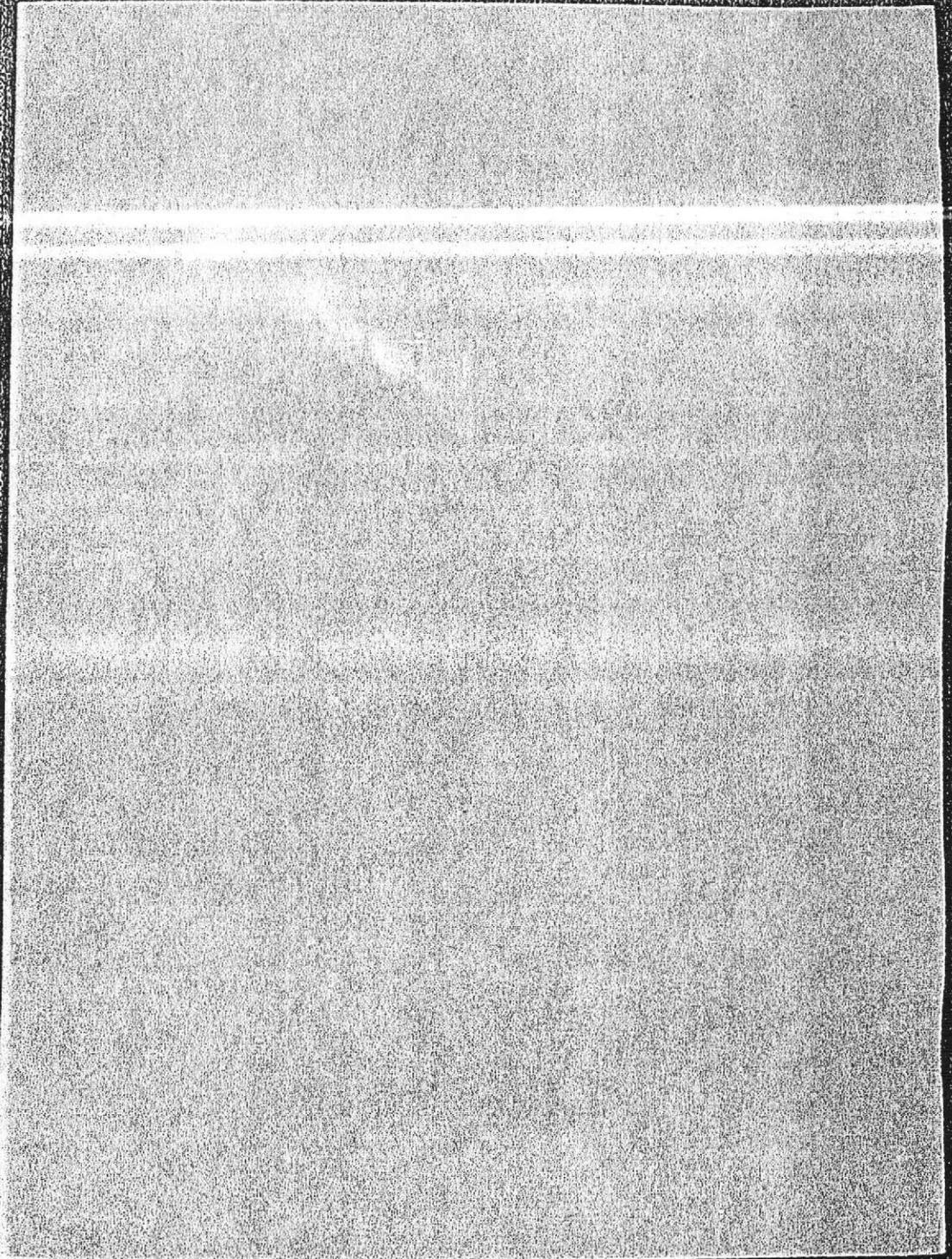
Film Specifications	
Polymer	(b)(4)
Film Thickness	(b)(4)
Pore Size	(b)(4)
Molecular Weight (Mw) Post-processing	(b)(4)
Absorption Rate	(b)(4)
Water Content	(b)(4)
Sterility	(b)(4)
Polymer Specifications	
Residual Level of Mfg. Reagents	(b)(4)
Residual Level of (b)(4) (b)(4)	(b)(4)
Sulfur	(b)(4)

Like the predicate TephafLEX film, the proposed film degrades (b)(4) (b)(4). *In vivo* animal

studies were performed in support of strength retention and film functionality. Results of this testing can be found in Section VI.

In summary, we believe the results of the bench testing and *in vivo* animal testing performed demonstrates the proposed (b)(4) TephaFLEX absorbable film is substantially equivalent to other currently marketed absorbable surgical film products.

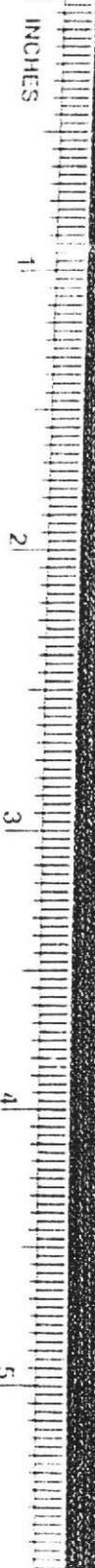
DJA 200048



INCHES

LABORATORY APPARATUS, FURNITURE
SCIENTIFIC INSTRUMENTS & CHEMICALS

VWR



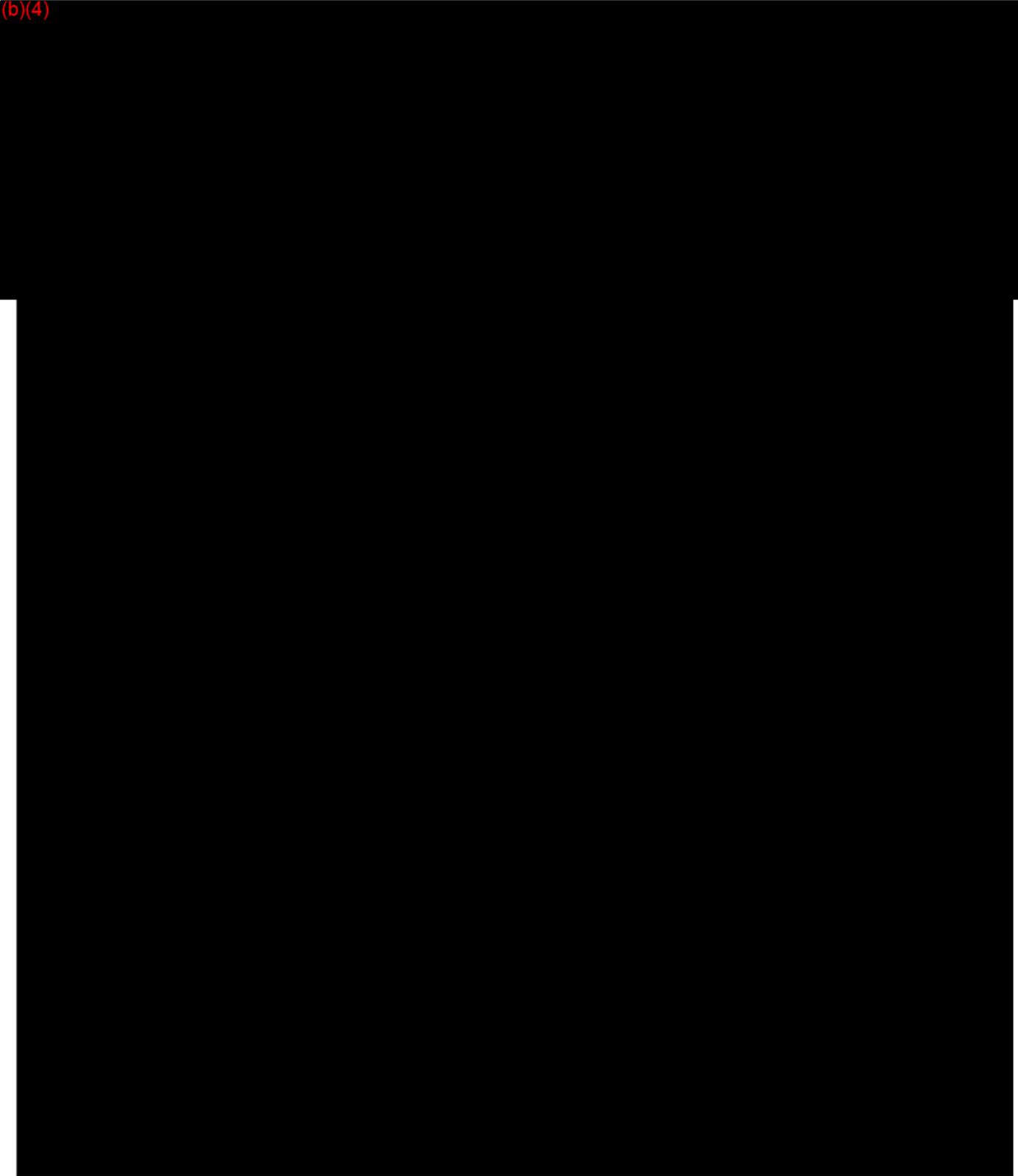
22

SECTION III

FUNCTIONAL TESTING

**Section III
Functional Testing**

(b)(4)



DJA x00050

DJA 200051

(b)(4) Testing



DJA 200052

Functional / Mechanical Testing

To evaluate the physical strength of the proposed (b)(4) TephaFLEX film, the following functional tests were performed:

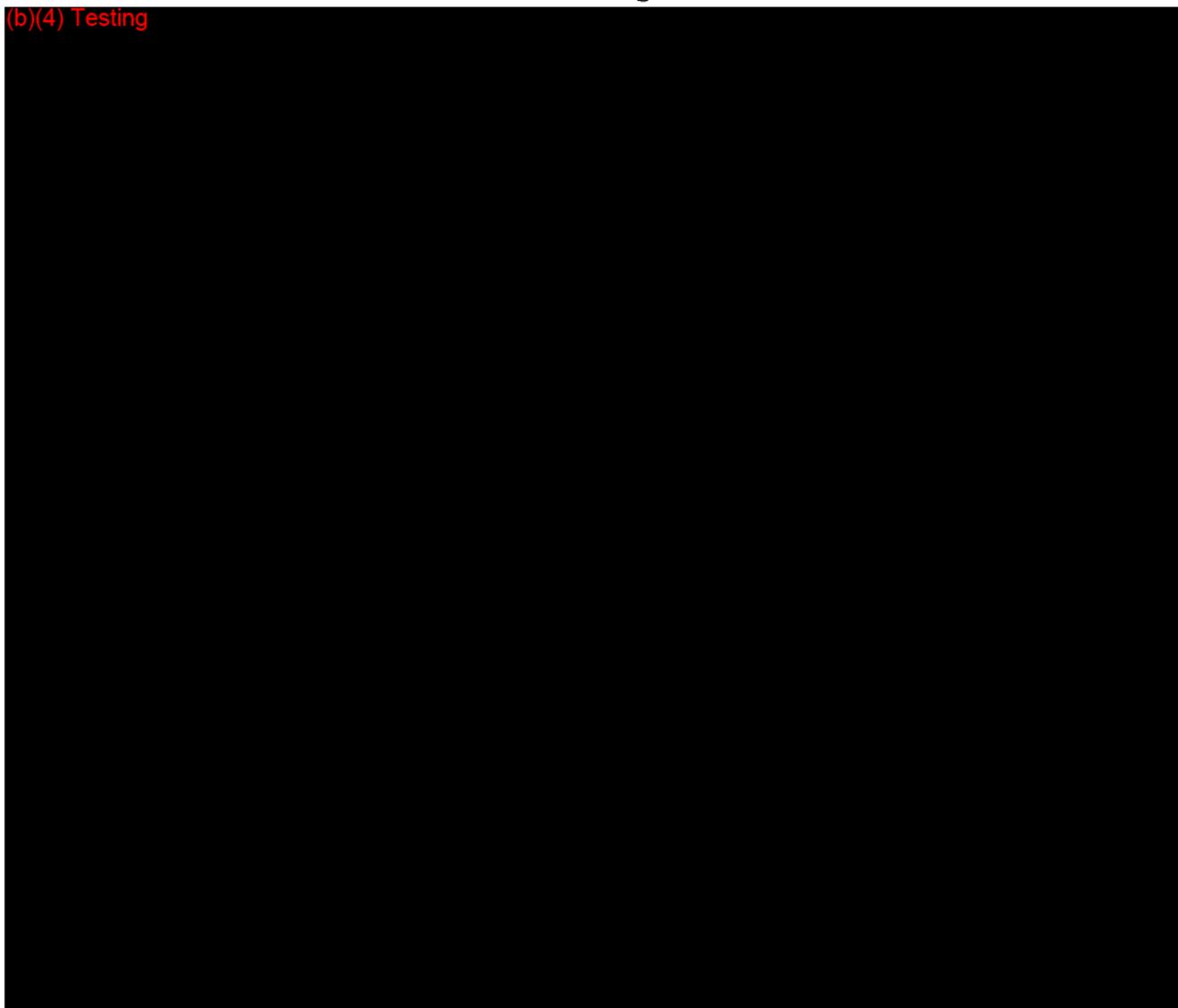
- Burst strength test
- Suture pull-out test
- Tensile strength test
- Tear resistance test

(b)(4) Testing



Burst Strength Test

(b)(4) Testing



(b)(4) Testing

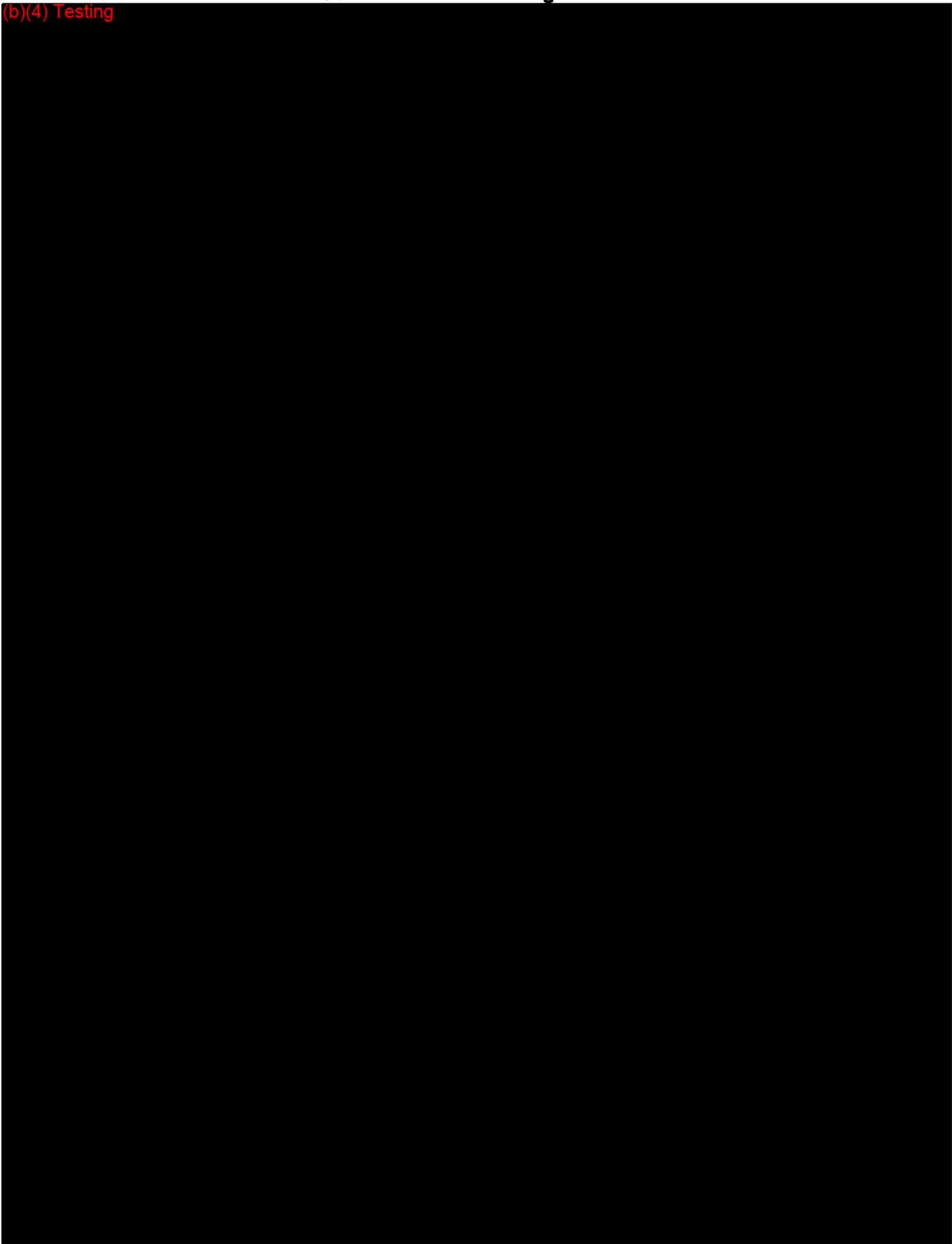


DJA
x00053

DJA 200054

Suture Pull-out Strength Test

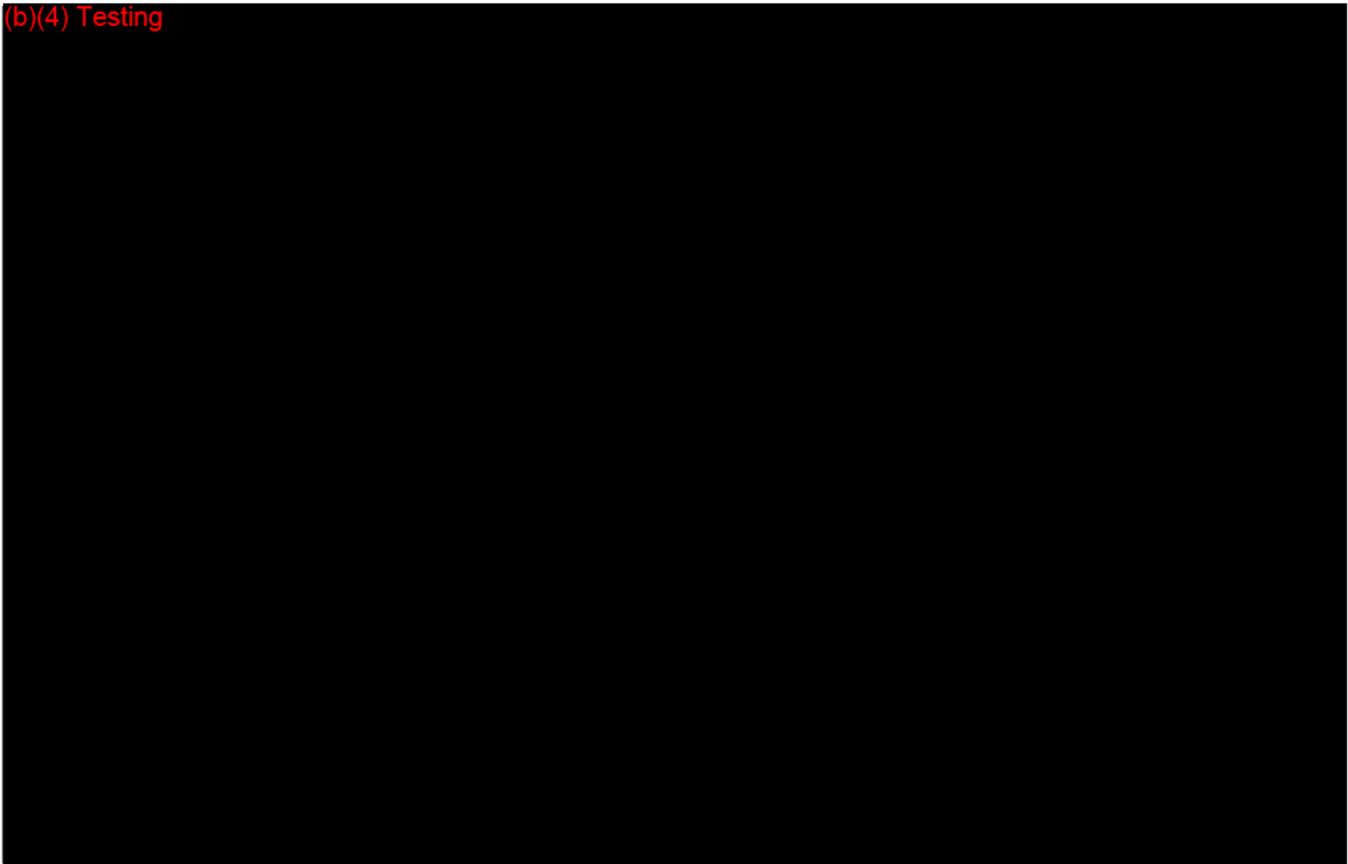
(b)(4) Testing



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DJA 200055

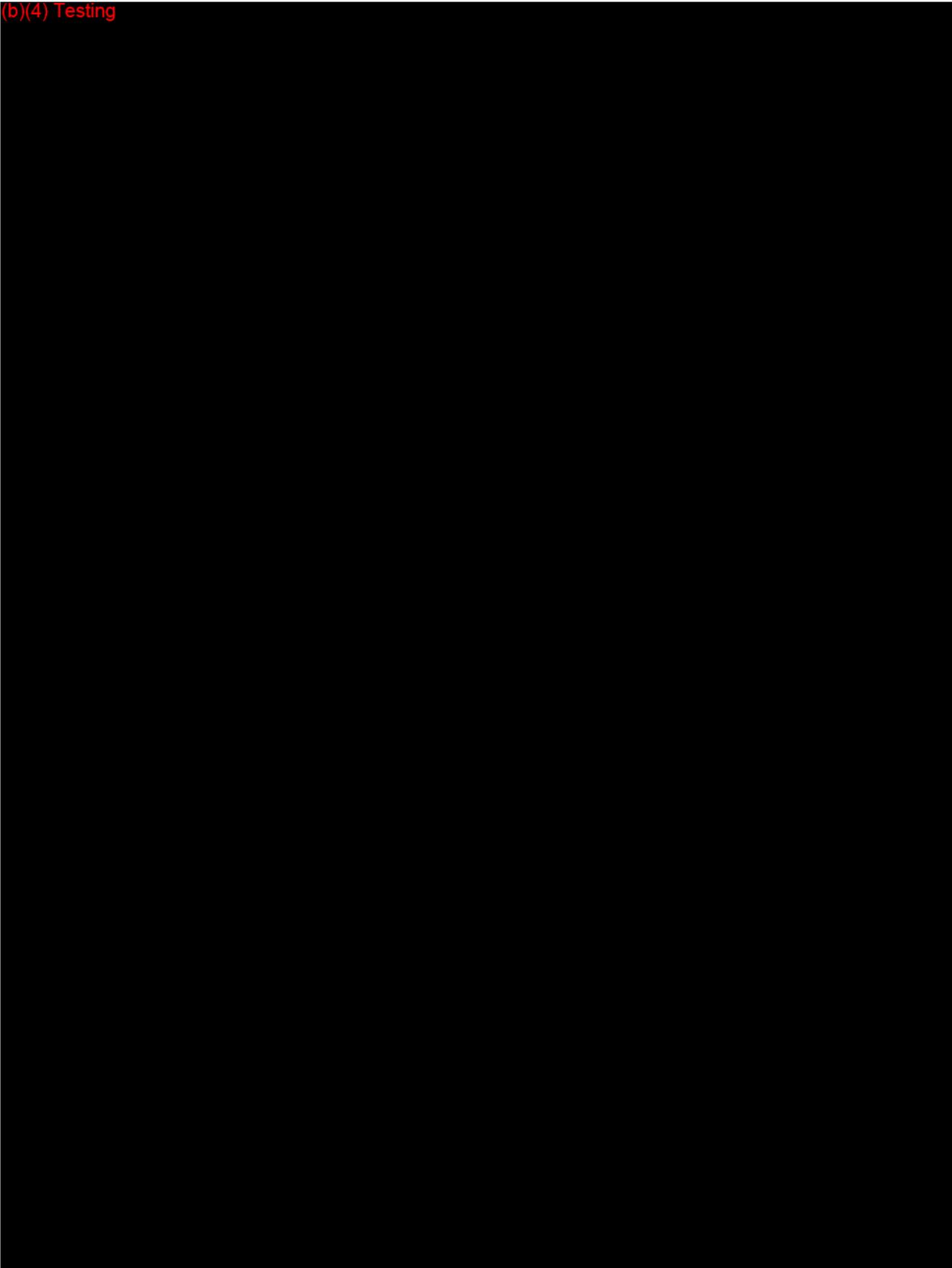
(b)(4) Testing



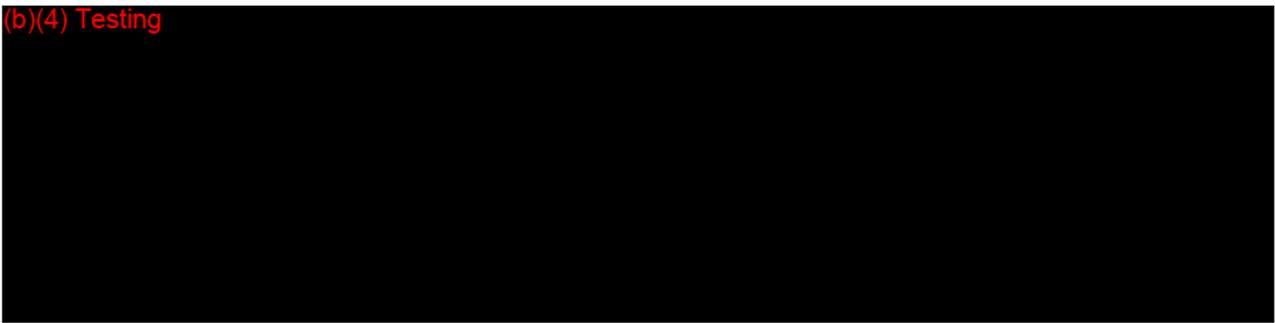
DJA 200056

Tensile Strength Test

(b)(4) Testing



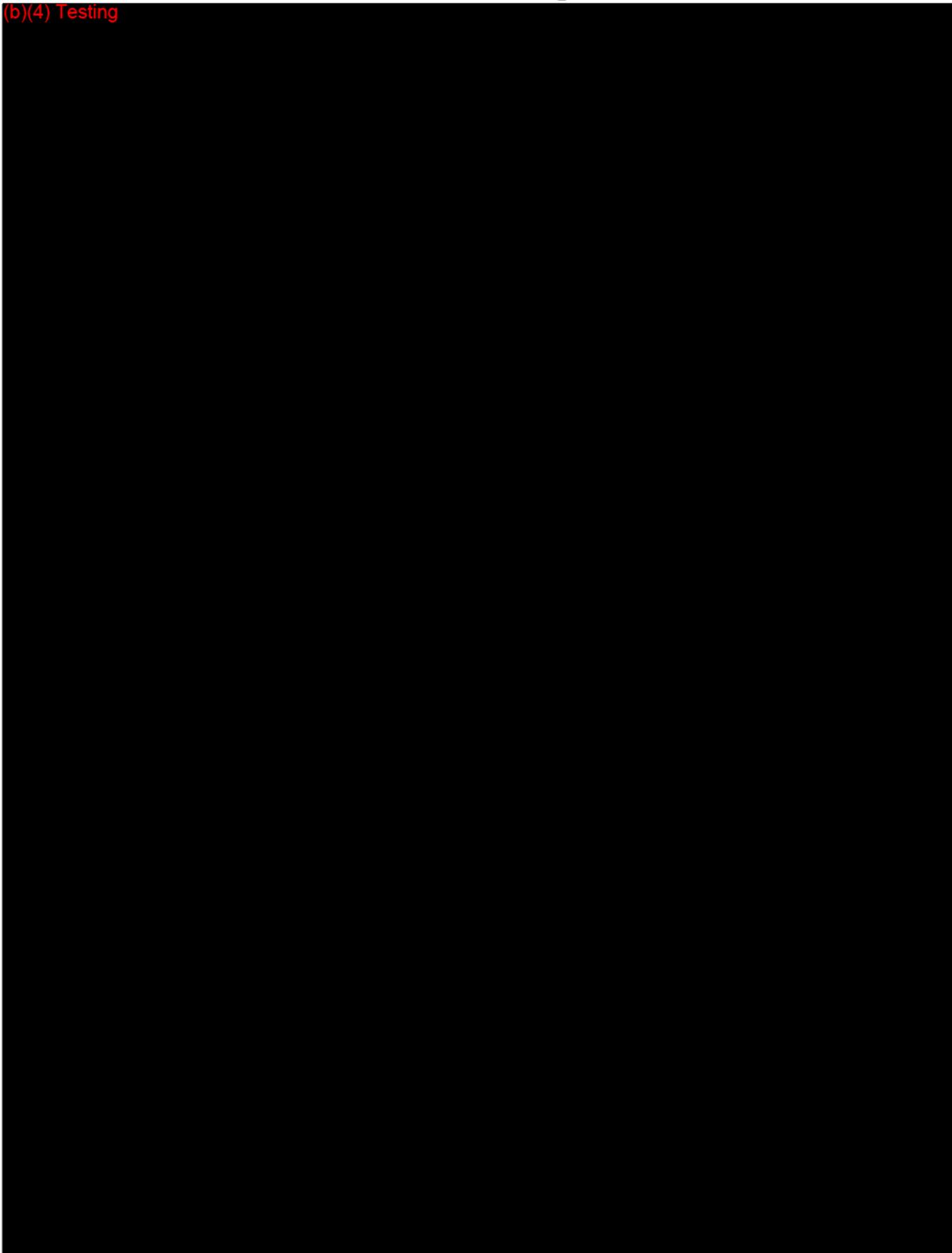
(b)(4) Testing



DJA 200058

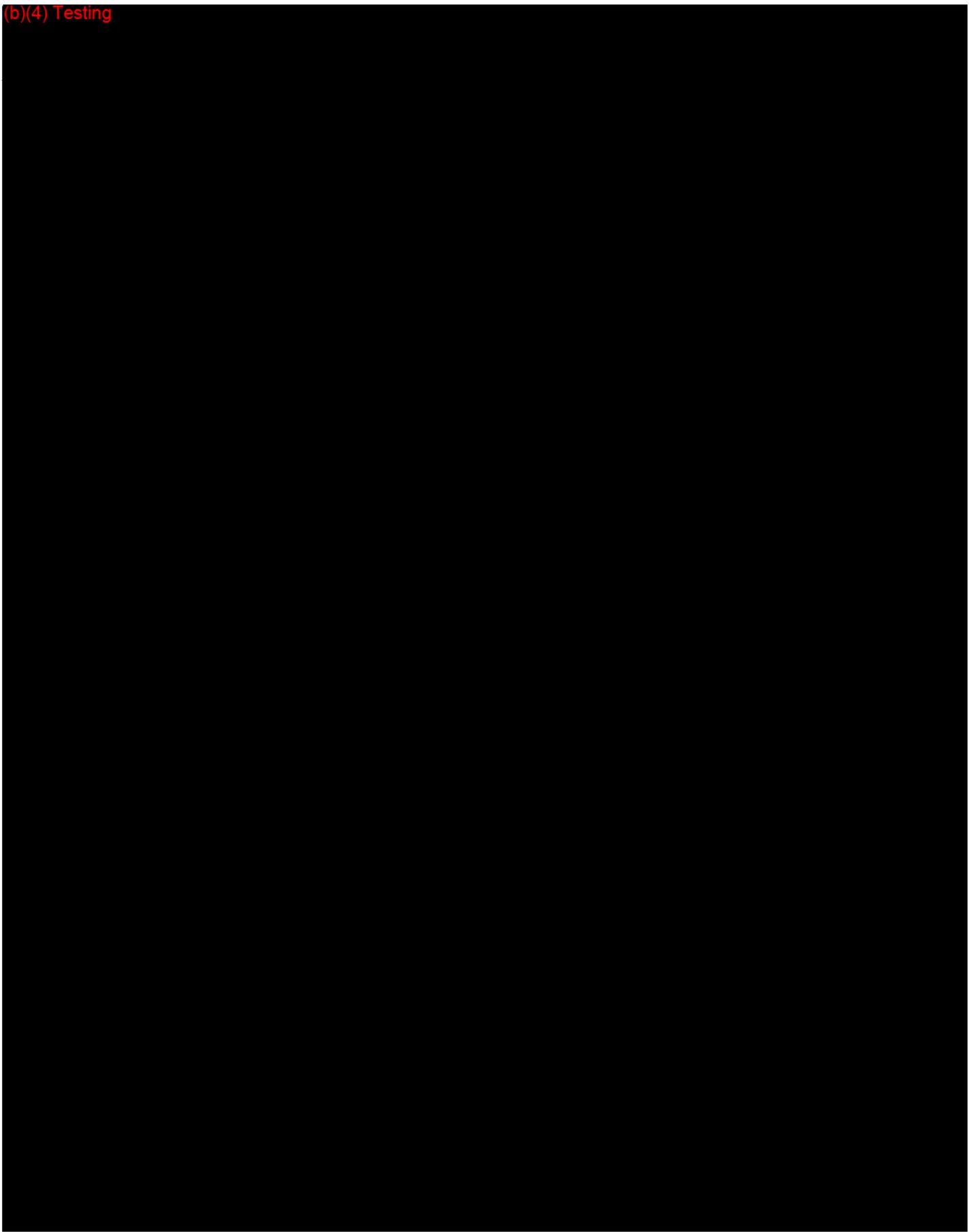
Tear Resistance Strength

(b)(4) Testing

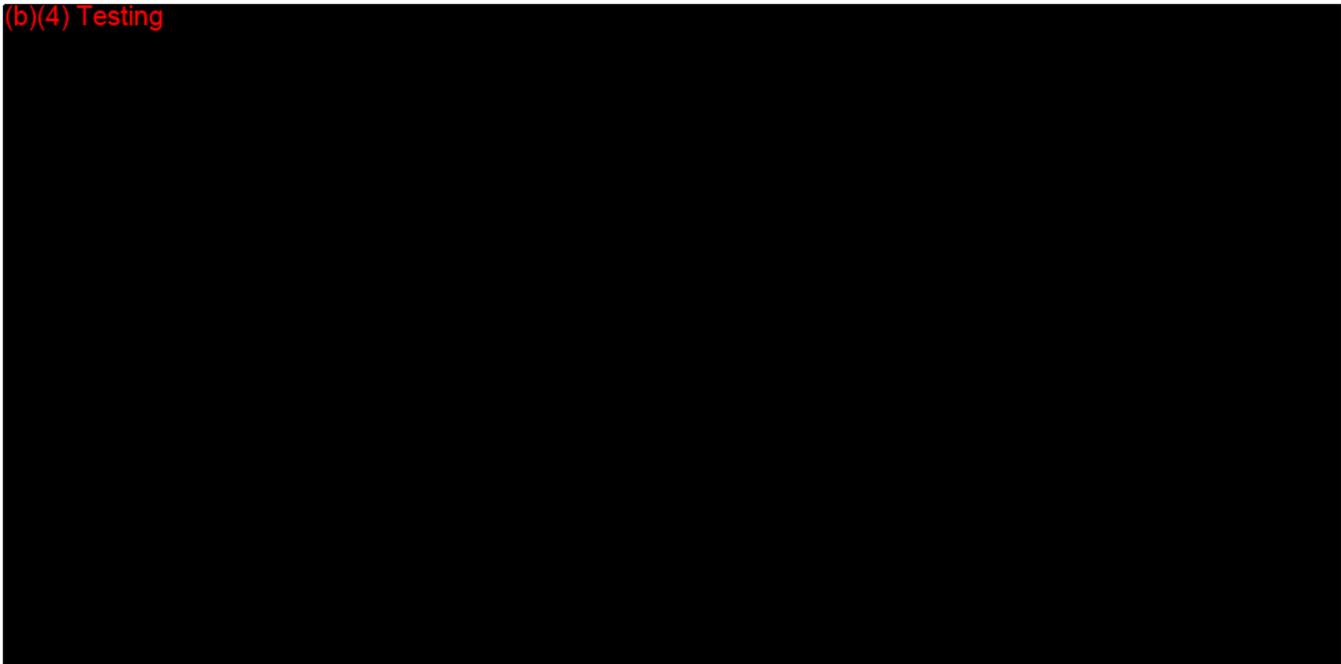


DJA 200059

(b)(4) Testing



(b)(4) Testing



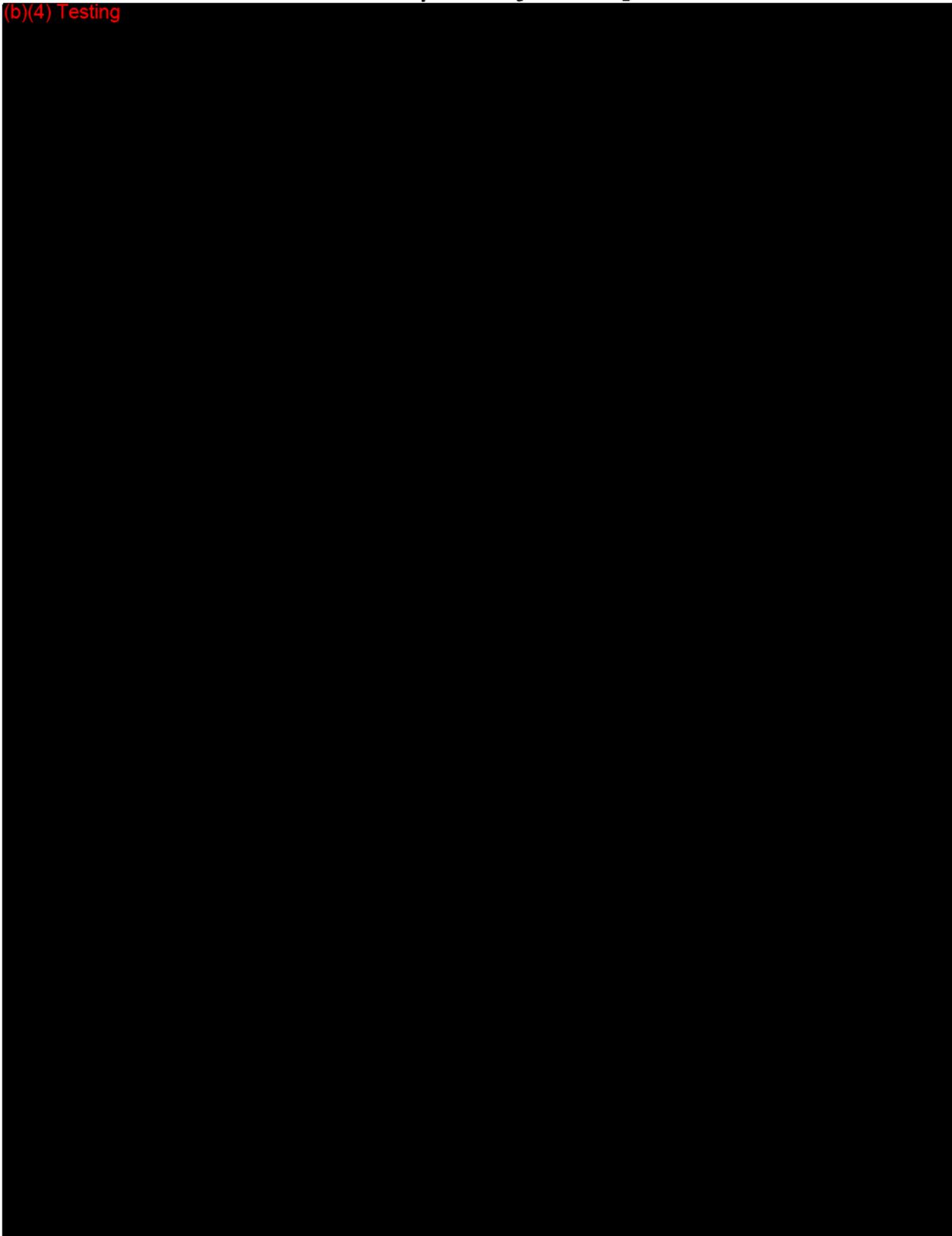
DJA
x00060

SECTION IV
BIOCOMPATIBILITY TESTING

DJA 200062

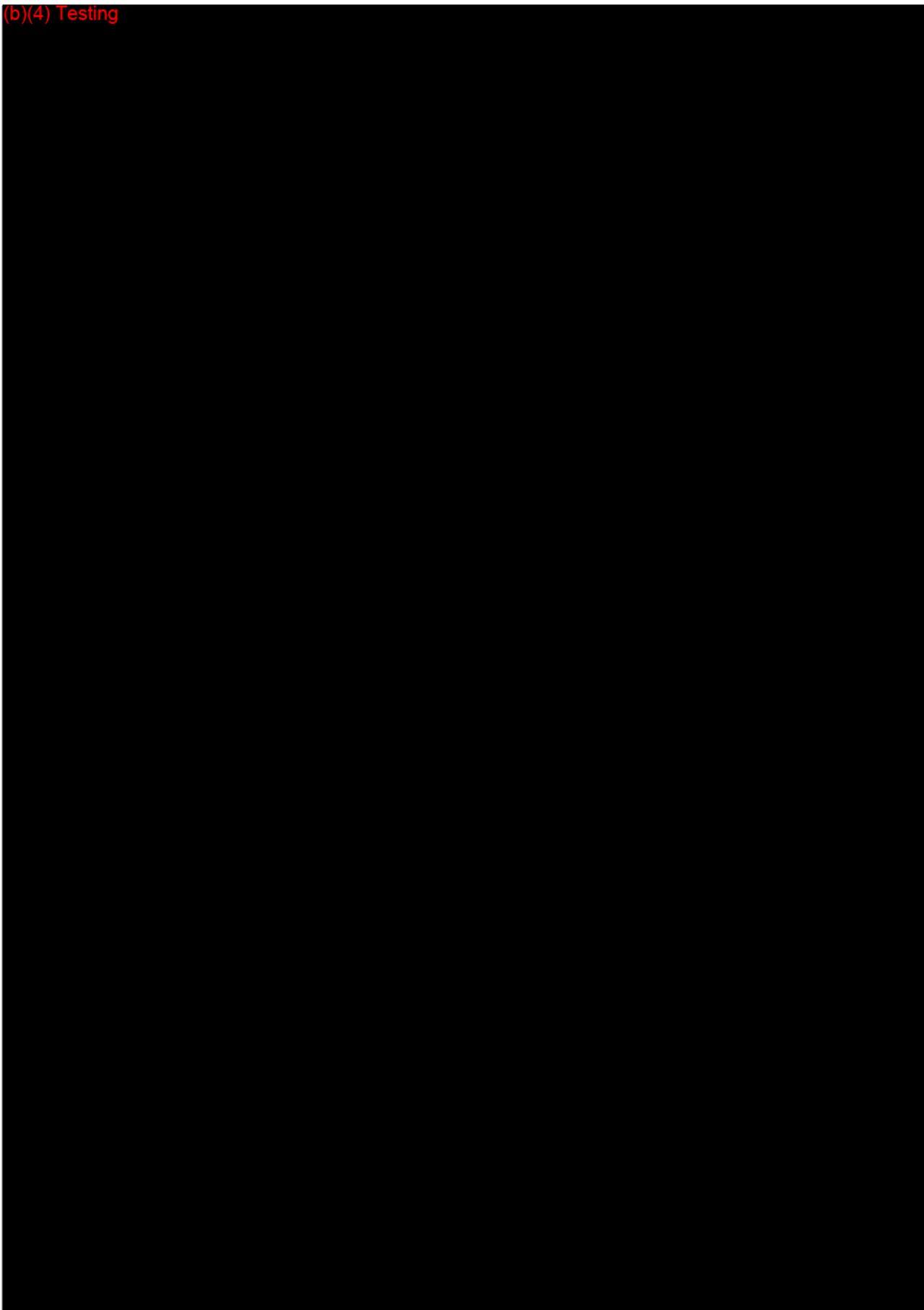
Section IV Biocompatibility Testing

(b)(4) Testing



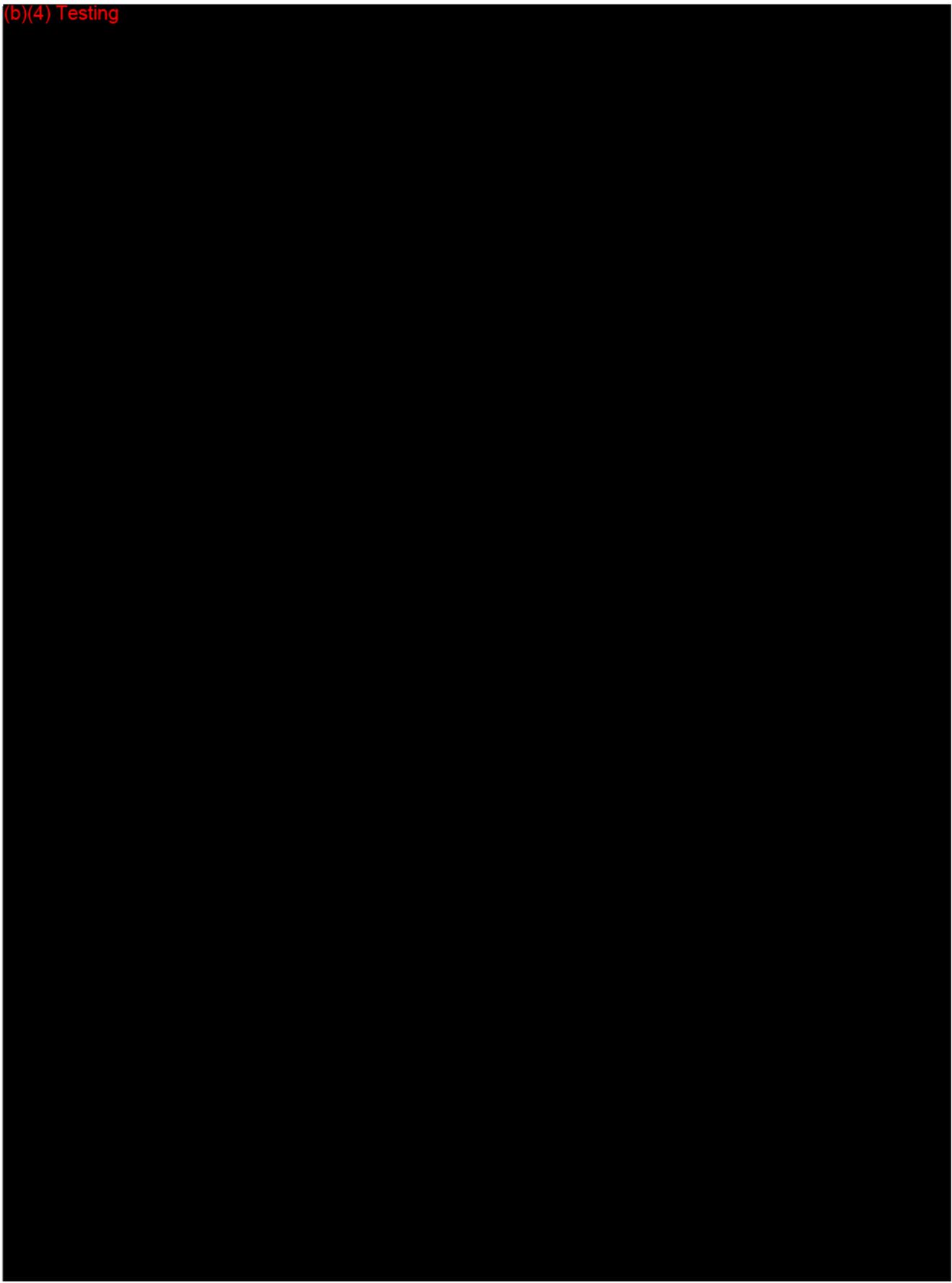
DJA 200063

(b)(4) Testing



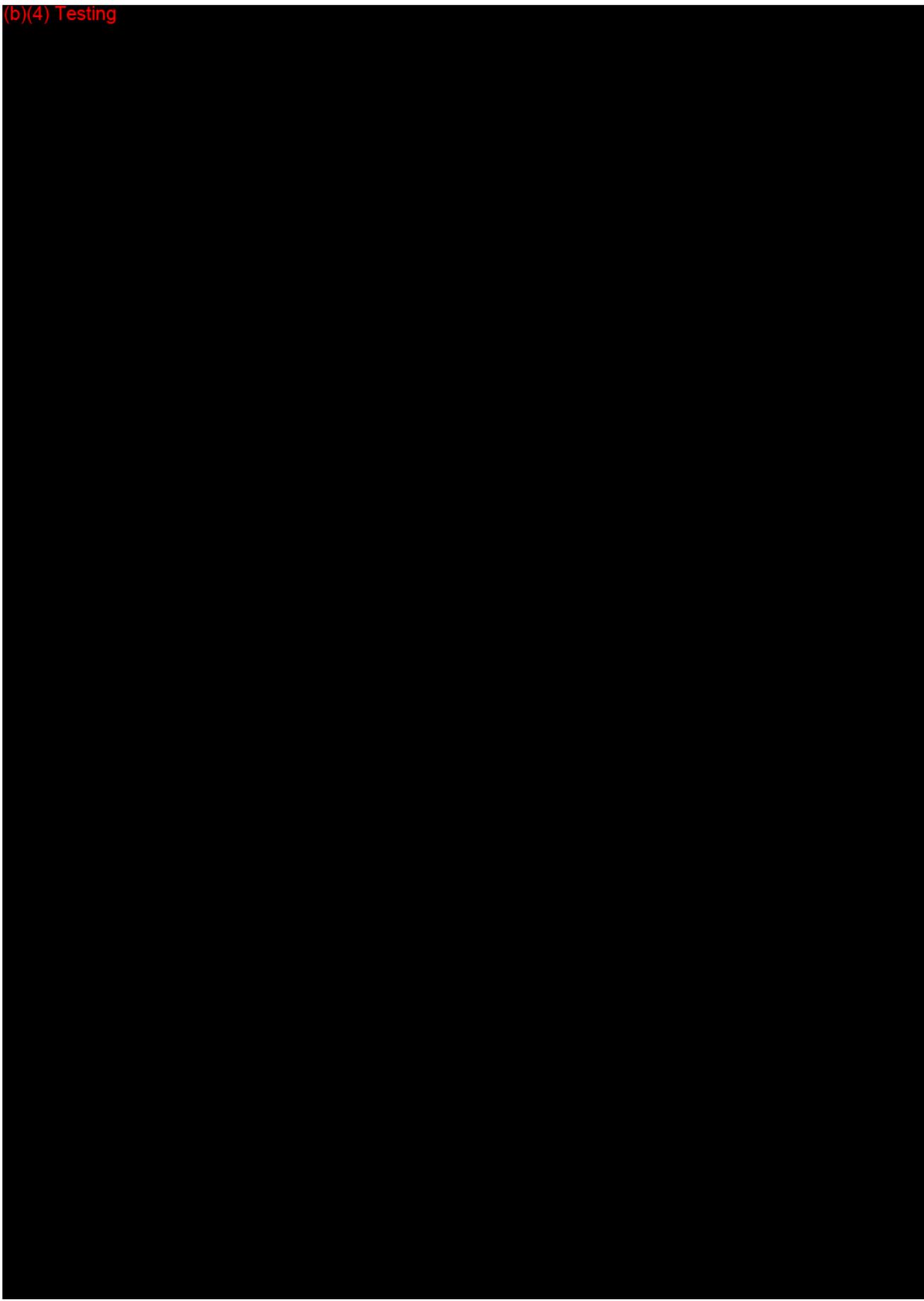
DJA 200064

(b)(4) Testing



DJA 200065

(b)(4) Testing



(b)(4) Testing



SECTION V

**PACKAGING, STERILIZATION AND
PYROGENICITY**

Section V Packaging and Sterilization

Packaging

All packaging materials and sealing methods used to package the proposed TephaFLEX surgical film are commonly used in the medical device industry. A packaging description for the device can be found below.

The TephaFLEX surgical film is an undyed, single use product that is terminally sterilized using (b)(4)

(b)(4)

Since the primary purpose of the package is to maintain device sterility and integrity, the proposed packaging will be subjected to testing to validate the device's labeled shelf life. For purposes of this application, the labeled shelf life is (b)(4). Package integrity testing will be performed in compliance with ANSI/AAMI/ISO 11607-1:2006 – Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems, and packaging systems.

Sterilization

(b)(4)

DJA 200069

(b)(4)



Pyrogenicity

(b)(4)



(b)(4)

The limitation for endotoxins for product release will comply with those set forth in FDA's recognized guidance (≤ 0.5 EU/mL).

SECTION VI
***In Vivo* Animal Testing**

ATTACHMENT A

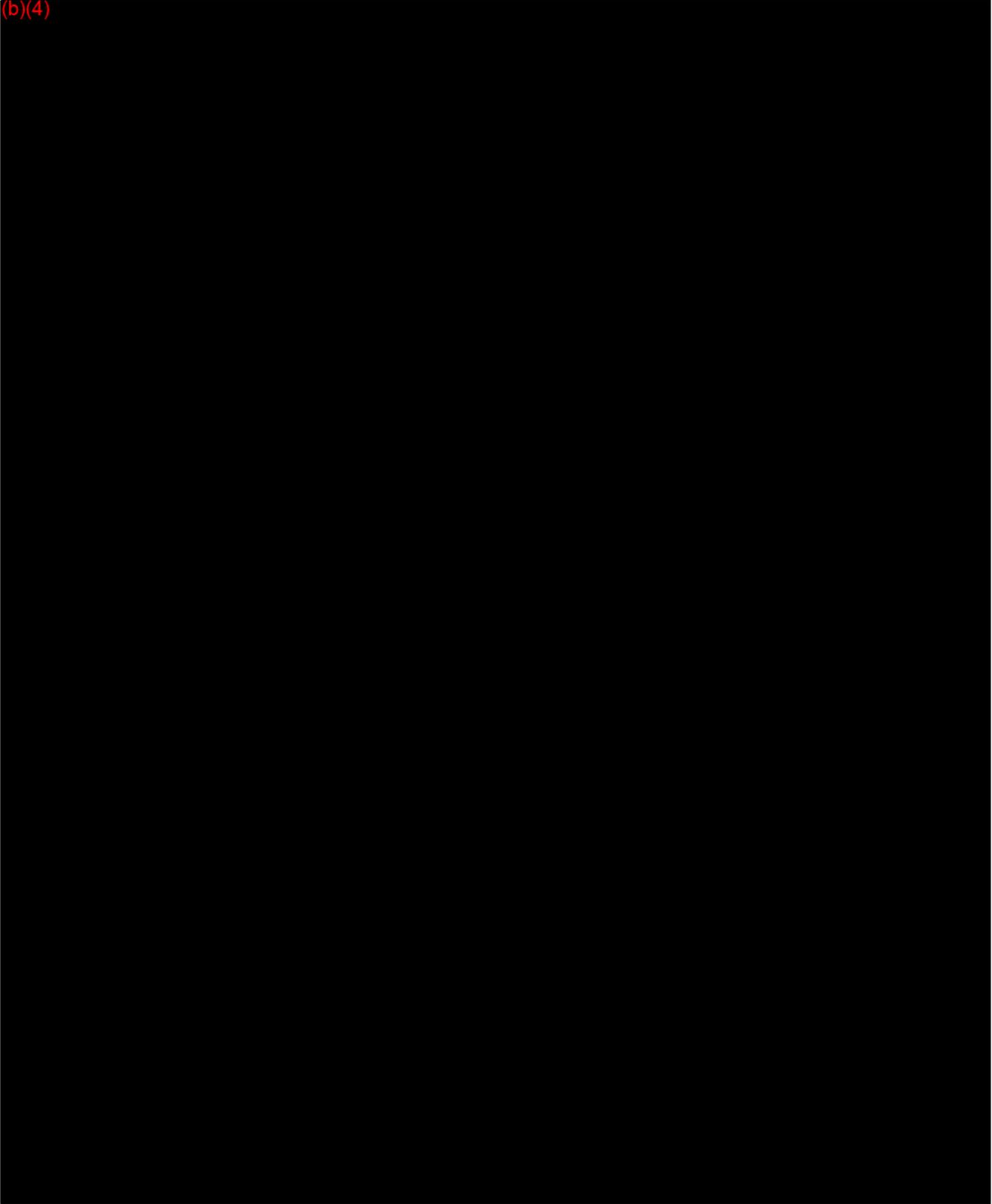
***In Vivo* FILM FUNCTIONALITY STUDY**

DJA 200072

Section VI

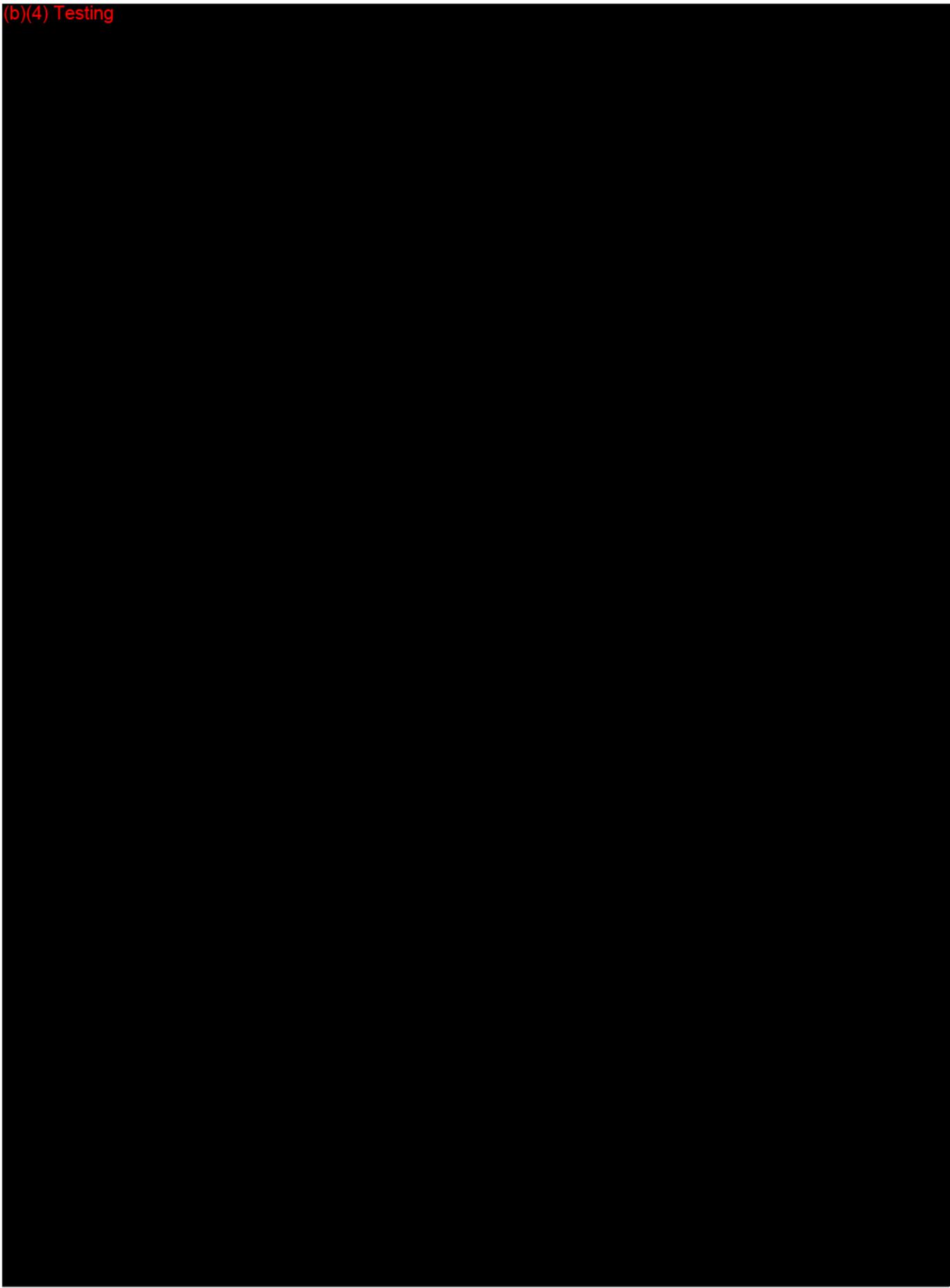
Attachment A
***In Vivo* Functionality Study**

(b)(4)



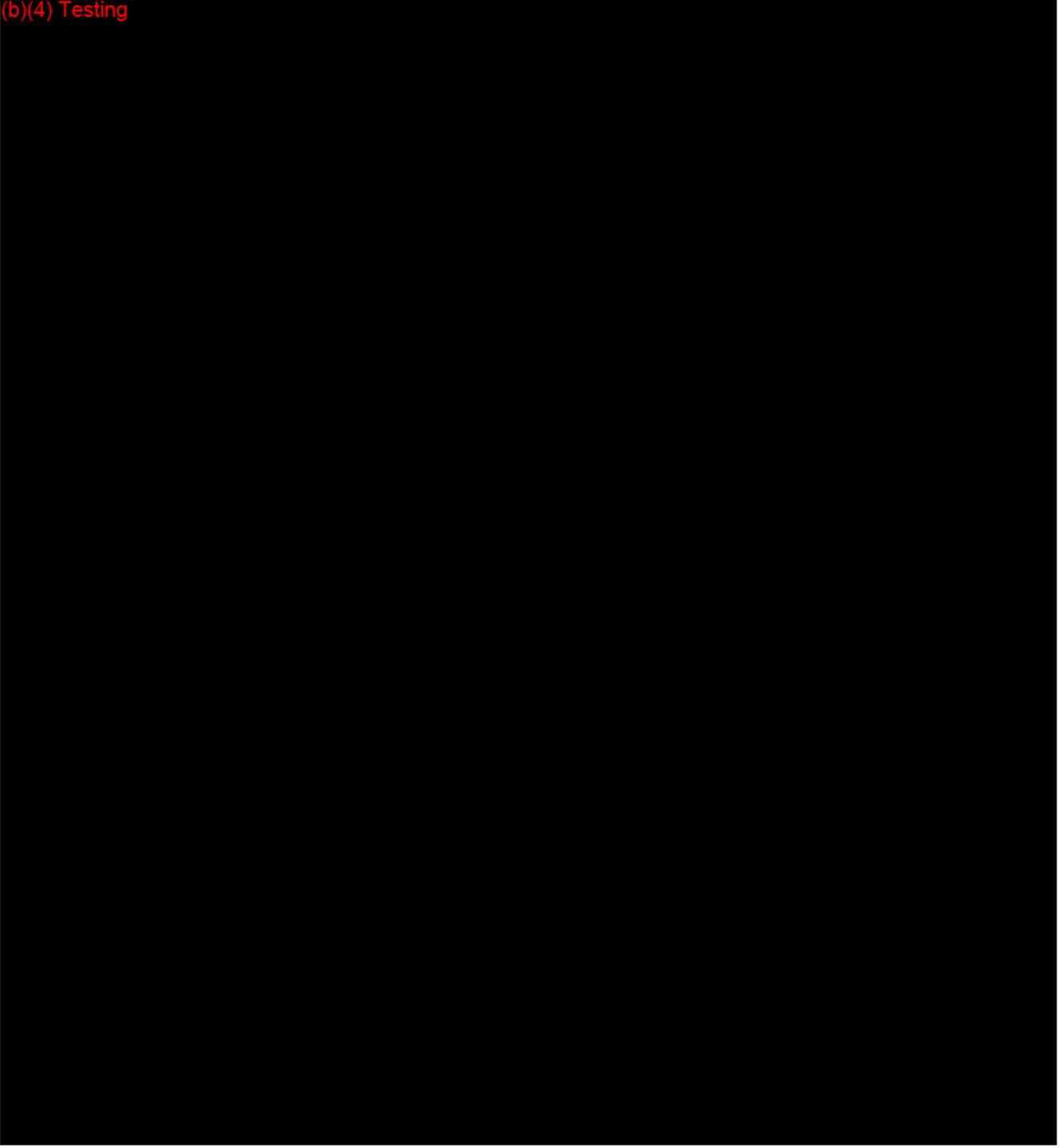
DJA 200073

(b)(4) Testing



DJA 200074

(b)(4) Testing



DJA 200075

(b)(4) Third
Party Testing

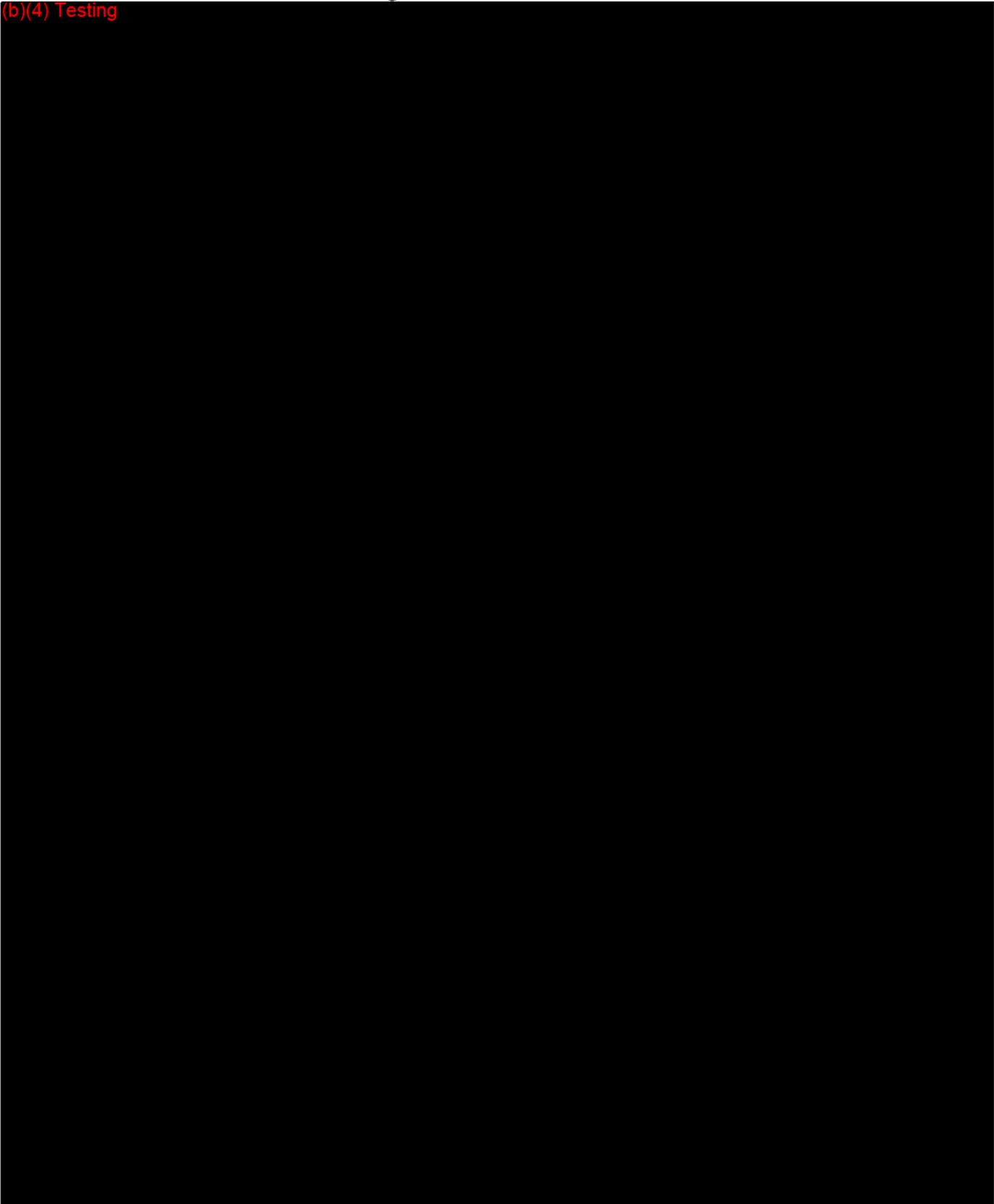
PROTOCOL/REPORT

ATTACHMENT B
BIODEGRADATION TEST

DJA x00103

Attachment B Strength Retention Study

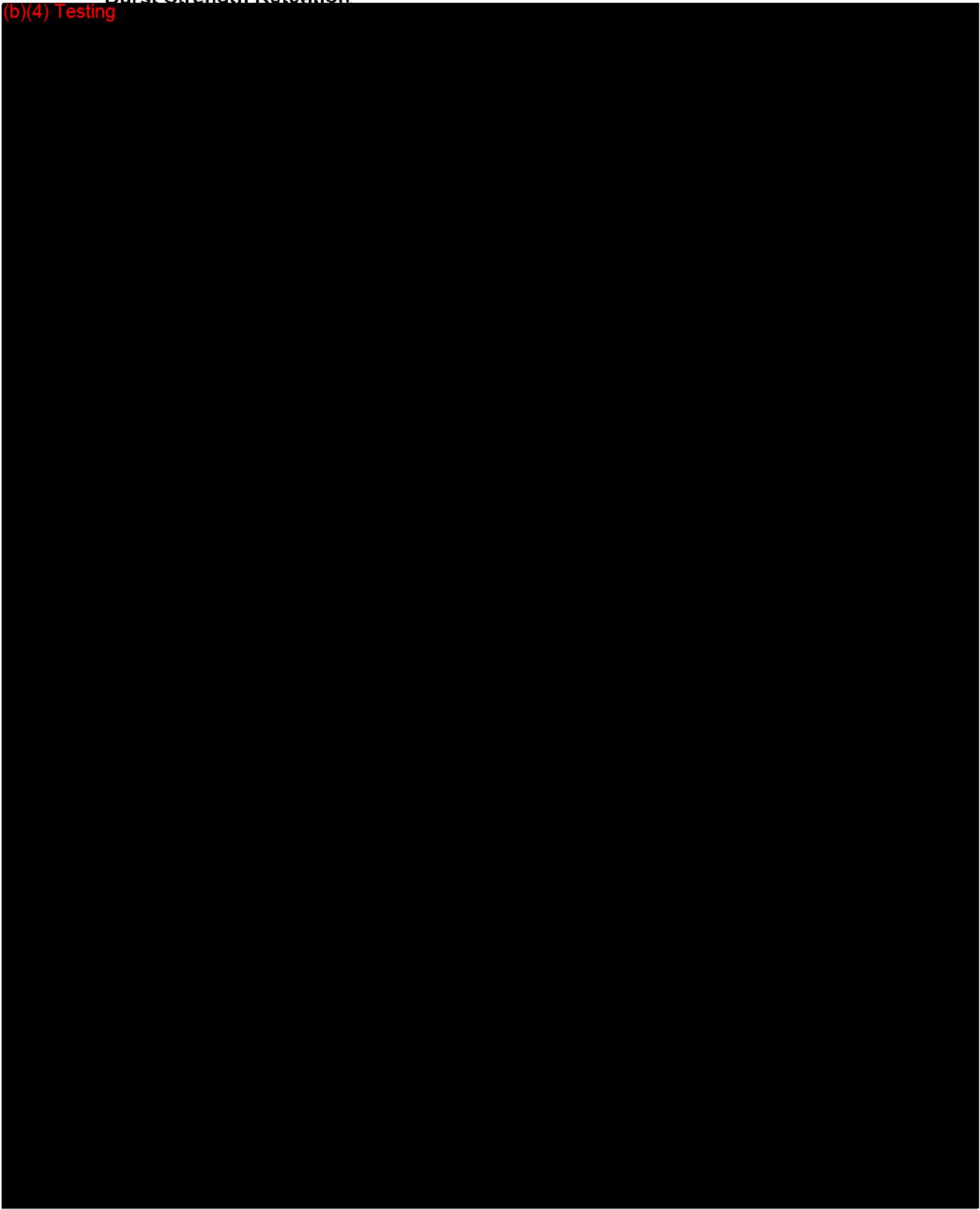
(b)(4) Testing



DJA 200104

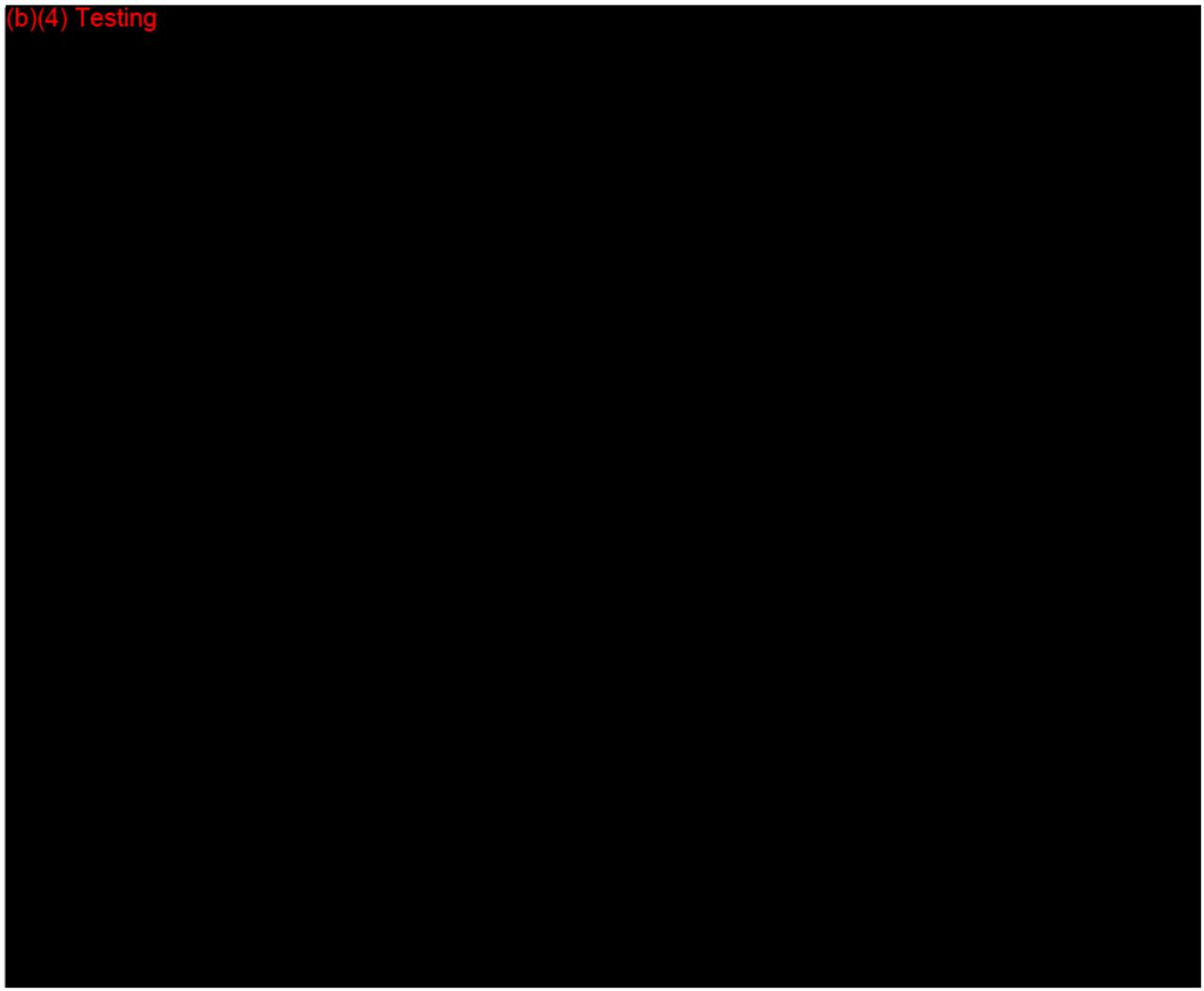
Burst Strength Retention

(b)(4) Testing



DJA
x00105

(b)(4) Testing



Tensile Strength Retention

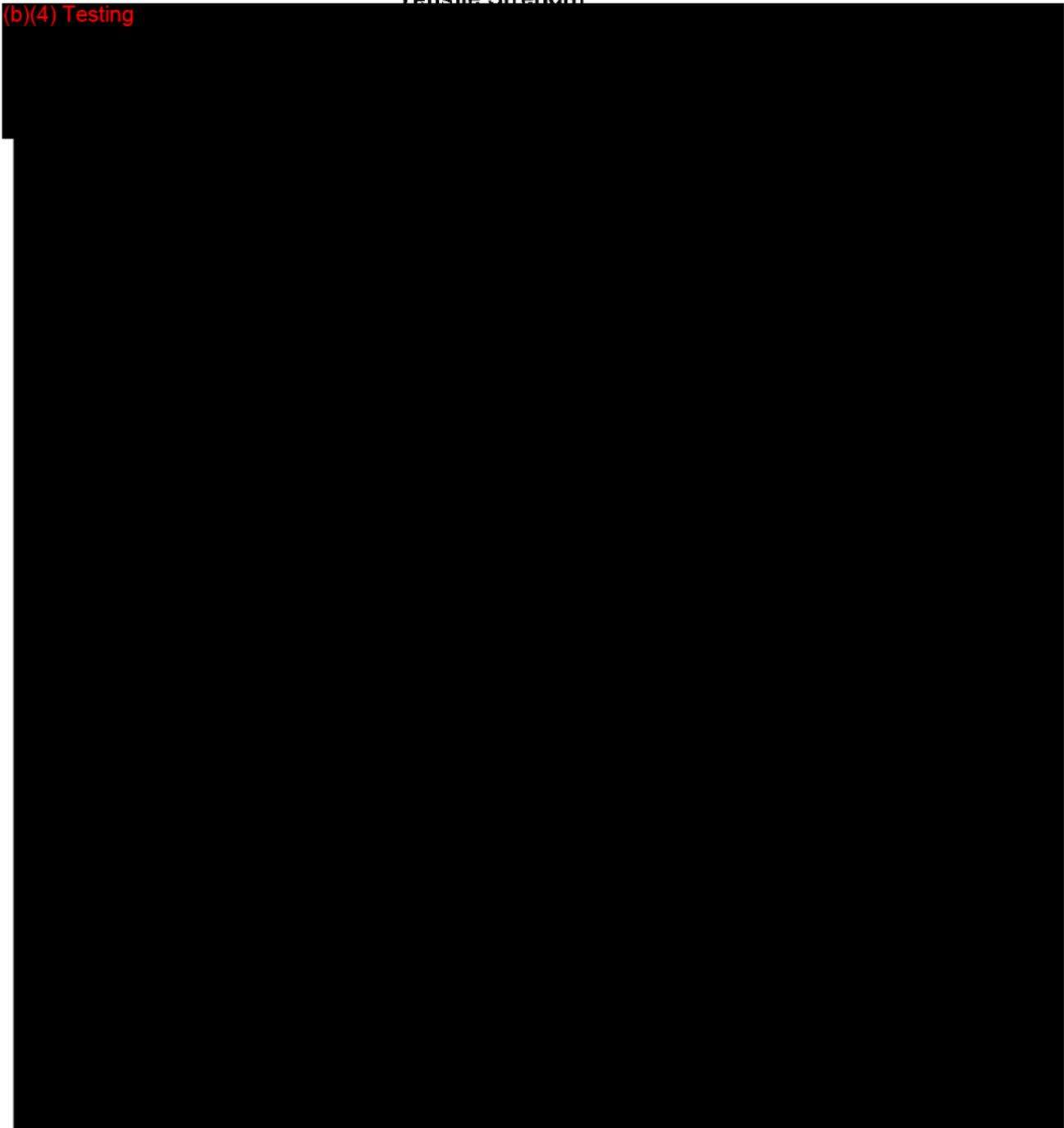
(b)(4) Testing



DJA 200106

Tensile Strength

(b)(4) Testing



80

DJA x00107

(b)(4)



HISTOLOGY REPORT

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SECTION VII
SUBSTANTIAL EQUIVALENCE

Section VII Substantial Equivalence

The proposed TephafLEX surgical film is intended to be used wherever temporary wound support is required, to reinforce soft tissues where weakness exists in the urological, gynecological, or gastrointestinal anatomy, or for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. The absorbable protective film also may help minimize the potential for tissue attachment to the device in case of direct contact with the viscera.

Tepha referenced FDA's Class II Special Control Guidance Document: Guidance for the Preparation of a Pre-market Notification Application for a Surgical Mesh when choosing appropriate predicate devices, and preparing the bench and animal test protocols used in support of this application. The information provided below, in conjunction with the detailed discussion of test results presented in other sections of this application, demonstrates the proposed device is equivalent in terms of functionality and safety to currently marketed predicate devices.

For purposes of this application, substantial equivalence for the proposed TephafLEX surgical film is based on similarities between it and the following predicate devices:

1. **TephafLEX Surgical Film – K072520**
2. **TephafLEX Absorbable Mesh – K070894**
3. **MAST Biosurgery, Inc., Surgi-Wrap Film – K031955, K050332**
4. **W.L. Gore – Gore Bioabsorbable Mesh – K033671**
5. **OsteoBiologics, Inc., Immix PlastiFilm – K032673**

Table 13 below contains a summarized comparison of the major functional and descriptive characteristics of the proposed TephafLEX film as compared to the currently marketed film products listed above.

Performance Results Burst Strength Suture Pullout Tear Resistance Tensile Strength	Substantially Equivalent	Unknown	Remains unchanged for approximately 8-10 weeks and then gradually absorbs	Unknown						
Packaging	(b)(4)	(b)(4)	(b)(4)	(b)(4)						
Sterilization	(b)(4)	(b)(4)	(b)(4)	(b)(4)						

To further evaluate the substantial equivalence of the proposed TephaFLEX film, we have employed the 510(k) "Substantial Equivalence Decision-Making Process" decision tree (attached). The answers to five questions from this decision tree lead to a determination of substantial equivalence for this device.

1. Does the new device have the same indication statements?

Yes. Indication statements for the proposed TephaFLEX film and the predicate devices outlined above are the same.

2. Does the new device have the same technological characteristics, e.g., design, materials, etc.?

Yes. In terms of material, product design, device manufacturing processes and mode of operation, the proposed TephaFLEX film is identical to the currently cleared TephaFLEX surgical film and equivalent to the SurgiWrap and PlastiFilm products.

3. Are the Descriptive Characteristics Precise Enough to Ensure Equivalence?

No. Although the technological characteristics and materials utilized in the proposed device are identical to those of the current TephaFLEX film, (b)(4) (b)(4) to demonstrate that the performance of the proposed device is substantially equivalent to the predicate devices.

4. Are Performance Data Available to Assess Equivalence?

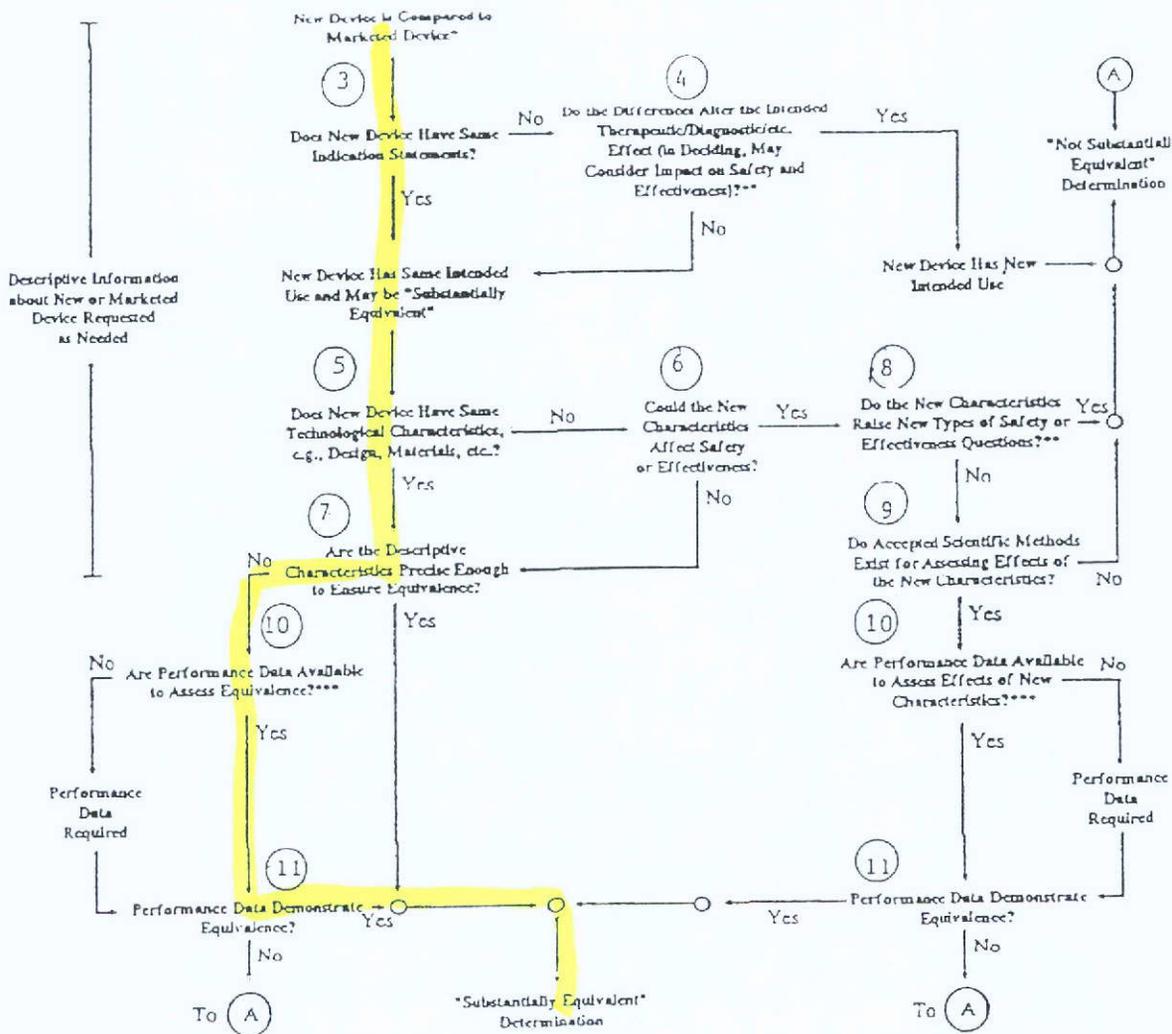
Yes. Performance data in support of the proposed device are available. Specifically, bench testing and *in vivo* animal testing were performed. A description of the bench testing conducted along with the test results can be found in Section III. A summary of the *in vivo* animal testing is located in Sections IV and VI. Additionally, labeling is provided with the product that defines the proper use of the device.

5. Performance data demonstrate equivalence?

Yes. Test results demonstrate the technological characteristics of the proposed device do not result in any new safety or effectiveness issues when used for the proposed indication. We believe, therefore, the proposed device is substantially equivalent to the currently marketed predicate devices discussed above.

DJA X00126

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-Amendments or reclassified post-Amendments) devices is unclear.
- ** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- *** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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SECTION VIII
PROPOSED DEVICE LABELING

FILM INSTRUCTIONS FOR USE

DRAFT

INSTRUCTIONS FOR USE TephaFLEX® Surgical Film

DESCRIPTION

TephaFLEX surgical film is an absorbable film prepared from poly-4-hydroxybutyrate (P4HB). The film is available in solid sheets in sizes ranging from 25mm x 25mm to 300mm x 300mm. The thickness of the film is 60 to 200 microns and may be cut to the shape or size desired for a specific application.

INDICATIONS FOR USE

TephaFLEX Surgical Film is designed to be used wherever temporary wound support is required, to reinforce soft tissues where weakness exists in the urological, gynecological or gastroenterological anatomy, or for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. The absorbable protective film also may help minimize the potential for tissue attachment to the device in case of direct contact with the viscera.

WARNINGS

TephaFLEX film is an absorbable product that will degrade over time. In repairs where permanent wound support is required, or if the repair requires a high degree of strength retention over a prolonged period of time, the film should be used in conjunction with an overlay patch to provide the long term mechanical strength required.

The safety and effectiveness of the TepahFLEX Absorbable Film used to reduce the incidence, extent and severity of postoperative adhesions have not been established in prospective, randomized clinical trials.

Device manufacture involves exposure to tetracycline hydrochloride and kanamycin sulfate. The safety and product use for patients with hypersensitivities to these antibiotics is unknown.

PRECAUTIONS

User should be familiar with surgical procedures and techniques, including strength requirements and film size and thickness choices. Improper size selection, placement, positioning, and fixation of the devices can cause subsequent undesirable results. The surgeon is to be familiar with the devices and the surgical procedure prior to performing surgery.

ACTIONS

TephaFLEX surgical film degrades through a process of hydrolysis and hydrolytic enzymatic degradation. It has been developed to minimize the variability of absorption rate (loss of mass) and strength retention, and provide wound support throughout the expected period of healing.

Implantation studies indicate the following strength retention over time:

<i>In Vivo</i> Mechanical Properties* - Burst Strength				
Implantation Time Point	60 micron TephaFLEX Film	% Strength Retention	200 micron TephaFLEX Film	% Strength Retention
Time 0	11.46	100	20.93	100
3 Weeks	3.27	29	17.01	81
6 Weeks	1.97	17	8.06	39

* Full degradation is essentially complete within 12-15 months

STERILITY

TephaFLEX surgical film is sterilized by ethylene oxide gas (EO). Product is sterile unless package has been opened or damaged. **DO NOT RESTERILIZE.** Discard opened or unused containers.

DIRECTIONS FOR USE

The TephaFLEX film may be cut to the shape or size desired for each specific application. Some surgeons prefer to suture a piece larger than the defect into position over the defect. The device should be sutured in place around its perimeter to assure proper positioning and to prevent film migration or folding. Suturing should be performed in such manner leaving at least ¼ inch of material between the location of the passage of each stitch through the device and the closest portion of the edge.

STORAGE

Store in a cool, dry place.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DJA x00129

PACKAGE LABELING

DJA x00131

DRAFT PACKAGE LABEL

Tepha Medical Devices, Incorporated

99 Hayden Avenue, Suite 360
Lexington, MA 02421
781-357-1700

TephaFLEX® Absorbable Surgical Film

Catalog Number: X00-0XX-XX
Quantity: XX

XXmm x XXmm, Undyed

Single Use STERILE EO See Directions for Use

Store at Room Temperature

Rx Only

Lot: XX-YYMMDD-XX
Use Before: MM-XX-YYYY

SECTION IX
PREDICATE DEVICE LABELING

K 033671

510(k) Premarket Notification
Indication For Use

GORE BIOABSORBABLE MESH

INDICATION FOR USE

510(k) Number (if known): _____

Device Name: GORE BIOABSORBABLE MESH

Intended Use / Indication For Use: The GORE BIOABSORBABLE MESH is intended for use in the reinforcement of soft tissue. Examples of applications where the GORE BIOABSORBABLE MESH may be used include, but are not limited to:

Hernia repair (inguinal, femoral, umbilical, abdominal, diaphragmatic, incisional, epigastric, gastroesophageal, hiatal, intermuscular).

Colon, rectal, urethral, and vaginal prolapse

Muscle flap reinforcement

Perforated tissue repair

General tissue reconstruction's (pelvic floor, periosteum, thoracic wall, bladder, suture line reinforcement, tissue deficit, etc.).

Prescription Use (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

Page 1 of 1

510(k) Number K033671

DJA X00133

DJA 200134

K033671 1/2/3
GORE BIOABSORBABLE MESH

510(k) Premarket Notification
510(k) Summary of Substantial Equivalence

Device Description

The GORE BIOABSORBABLE MESH is used to reinforce soft tissue during the phases of wound healing by filling or bridging soft-tissue void spaces or defects. The GORE BIOABSORBABLE MESH elicits a physiological tissue response, which fills the defect with native tissue and gradually absorbs the device.

GORE® BIOABSORBABLE MESH is comprised of a microporous structure of synthetic bioabsorbable poly (67% glycolide: 33% trimethylene carbonate by weight) (PGA: TMC) copolymer fiber. This is the same material used in the predicate device (GORE DRAPEABLE ST Regenerative Membrane, K013346, cleared December 19, 2001 and SEAMGUARD, K030782 cleared April 21, 2003).

As packaged, the GORE BIOABSORBABLE MESH is a tailorable, bioabsorbable material intended to be a temporary bridge of defects until the absorptive nature of the device stimulates the body to fill the defect with native tissue. The device is available in sheets and preformed, three-dimensional shapes. The GORE BIOABSORBABLE MESH is provided STERILE for single use only.

Due to the absorptive nature of the GORE BIOABSORBABLE MESH, an overlay patch should be used in corrections requiring high strength (e.g., groin hernia repair)

Indication for Use

The GORE BIOABSORBABLE MESH is intended for use in the reinforcement of soft tissue. Examples of applications where the GORE BIOABSORBABLE MESH may be used include, but are not limited to:

Hernia repair (inguinal, femoral, umbilical, abdominal, diaphragmatic, incisional, epigastric, gastroesophageal, hiatal, intermuscular).

Colon, rectal, urethral, and vaginal prolapse

Muscle flap reinforcement

Perforated tissue repair

General tissue reconstruction's (pelvic floor, periosteum, thoracic wall, bladder, suture line reinforcement, tissue deficit, etc.)



Confidential

CJA X00135

INSTRUCTIONS FOR USE

DESCRIPTION

The IMMIX™ PlastiFilm is a polymeric surgical mesh device, which is produced using an amorphous 75/25 poly(D,L-lactide-co-glycolide) and a plasticizer (either triethyl 2-acetylacrylate or tributyl 2-acetylacrylate). The IMMIX™ PlastiFilm is provided with and without nonporous holes. The holes may be aligned, offset, or random patterns, and the borders of the sheets may be attached with suture material. Additionally, the device may be cut with scissors to obtain desired shapes and sizes.

INDICATIONS

The IMMIX™ PlastiFilm is to be used wherever temporary wound support is required, to reinforce soft tissue where weakness exists, or for the repair of hernia or other fascial defects that require the addition of a reinforcing, or bridging material to obtain the desired surgical result. This includes, but is not limited to the following procedures: vaginal prolapse repair, colon and rectal prolapse repair, reconstruction of the pelvic floor and sacral colposuspension.

CONTRAINDICATIONS

There are no contraindications known for the use of IMMIX™ PlastiFilm.

WARNINGS

- Do not use if the sterile barrier has been compromised in any way.
- Do not use if the expiration date has been exceeded.
- Do not use in the presence of an active infection.
- Use this device as supplied and according to the HANDLING AND DIRECTIONS FOR USE information provided.

PRECAUTIONS

- The IMMIX™ PlastiFilm is a single-use device (SUD). Do not reuse or resterilize.
- The IMMIX™ PlastiFilm is not intended for use in load bearing conditions.

ADVERSE EVENTS

There are no adverse events known to result from the use of IMMIX™ PlastiFilm.

HOW SUPPLIED

The IMMIX™ PlastiFilm provided sterile. Each device is individually packaged in a sealed tray using single-use packaging.

HANDLING AND DIRECTIONS FOR USE

IMMIX™ PlastiFolms are provided sterile and should be considered sterile unless the inner packaging has been opened or damaged. This product should not be resterilized. This device is for single patient use and should never be reused. Use IMMIX™ PlastiFilm aseptically according to the following surgical technique:

Maintaining Device Effectiveness

- Store in a cool, dry place away from objects that may damage the device packaging.
- Do not use if expiration date has been exceeded.
- Discard any unused IMMIX™ PlastiFilm.

Material Insertion

02/20/11

CD9

DJA x00136

2.4 Indications For Use (Form)

INDICATIONS FOR USE		
510(k) Number (if known):	<u>K032673</u>	
Device Name:	<u>IMMIX™ PlastiFilm</u>	
Indications For Use:		
<p>The IMMIX™ PlastiFilm is to be used wherever temporary wound support is required, to reinforce soft tissue where weakness exists, or for the repair of hernia or other fascial defects that require the addition of a reinforcing, or bridging material to obtain the desired surgical result. This includes, but is not limited to the following procedures: vaginal prolapse repair, colon and rectal prolapse repair, reconstruction of the pelvic floor and sacral colposuspension.</p>		
(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED) * * * * *		
Concurrence of CDRH, Office of Device Evaluation (ODE)		
 <i>Miriam C Provost</i> _____ (Division Sign-Off) Division of General, Restorative and Neurological Devices 510(k) Number <u>K032673</u>		
Prescription Use <u>X</u> (Per 21 CFR 801.109)	OR	Over-The-Counter Use _____

— Instructions for Use —
SurgiWrap™ MAST Bioreabsorbable Sheet

DESCRIPTION

The SurgiWrap™ MAST Bioreabsorbable Sheet is a biodegradable surgical mesh for trauma and reconstructive surgical procedures involving soft tissues. SurgiWrap™ MAST Bioreabsorbable Sheet is available in various sizes and thickness for use in maintaining the relative position of healing tissues. The implants maintain the stability of soft tissues during the healing period and minimize the attachment of tissue to the device. The SurgiWrap™ material is subsequently reabsorbed by the body once the soft tissues have healed. In this manner, it is possible to avoid a second surgical procedure that may otherwise be necessary to remove permanent implants. The implants are not intended for use where permanent implants are required.

MATERIAL

The SurgiWrap™ MAST Bioreabsorbable Sheet is made from the amorphous biodegradable copolymer 70:30 poly (L-lactide-co, DL-lactide). This copolymer degrades and resorbs *in vivo* by hydrolysis and is metabolized by the body into CO₂ and H₂O.

INDICATIONS

The SurgiWrap™ MAST Bioreabsorbable Sheet is to be used wherever temporary wound support is required, to reinforce soft tissues where weakness exists in the urological, neurological or gastroenterological anatomy, or for the repair of hernia or other mesal defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. This includes, but is not limited to the following procedures: abdominal support and bladder support, urethral and vaginal prolapse repair, colon and rectal prolapse repair, reconstruction of the pelvic floor and sacral colpo-suspension. The resorbable Protective Filtr minimizes tissue attachment to the device in case of direct contact with the viscera. The device is indicated for open and laparoscopic procedures. Laparoscopic procedures are limited to sizes from 0.02mm – 0.2mm thickness.

CONTRAINDICATIONS

The following are contraindications for use of SurgiWrap™ MAST Bioreabsorbable Sheet: Where permanent implants are needed.

Active infection.
Patient conditions including blood supply limitations, or latent infection.

STERILITY

SurgiWrap™ MAST Bioreabsorbable Sheet is sterilized by electron beam irradiation.

STORAGE AND HANDLING

DO NOT STORE AT TEMPERATURES ABOVE 120°F (49°C).

Use only if sterilization indicator square is RED.

Store at controlled room temperature 59–86°F (15–30°C).

Do not use if temperature indicator is BLACK.

WARNINGS

DO NOT USE in procedures where permanent implants are needed. These biodegradable devices provide temporary fixation and are not intended to replace normal healthy tissue.

Discard and DO NOT USE previously opened or damaged devices, and use only devices that are packaged in unopened and undamaged containers. **FOR SINGLE USE ONLY.**

- DO NOT USE if there is loss of sterility of the device.
- DO NOT RESTERILIZE.

PRECAUTIONS

- Improper selection, placement, positioning, and fixation of the device can cause subsequent undesirable results. The surgeon is to be familiar with the devices and the surgical procedure prior to performing surgery.
- The device can break or be damaged due to excessive activity or trauma. This could lead to failure of the device which could require additional surgery and device removal.
- The SurgiWrap™ MAST Bioreabsorbable Sheet can be cut with sterile scissors.

POSSIBLE ADVERSE EFFECTS

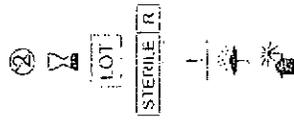
- Infection can lead to treatment failure.
- Neurovascular injuries can occur due to surgical trauma.
- Bending, fracture, loosening, rubbing, and migration of the fixation devices can occur as a result of excessive activity, trauma or load bearing.
- While rare, implantation of foreign materials can result in an inflammatory response or allergic reaction.
- Hematoma.
- Suture pull out.

SUTURING

- When suturing the SurgiWrap™ MAST Bioreabsorbable Sheet, suture the prosthetic material to the natural tissue by using the appropriate number of sutures uniformly spaced.
- Choose an appropriate size suture and needle for the defect to be reconstructed.
- Choose an appropriate size suture and needle for the prosthetic implant being utilized.
- Use minimal tension when pulling on suture line and placing knots.
- To avoid mechanical damage and suture hole elongation, smoothly pierce the SurgiWrap™ MAST Bioreabsorbable Sheet and follow the curve of the needle through the material. If the needle falls out of the needle hole following membrane puncture, the suture must be taken to pass the suture back through this original needle hole.
- Suture pull through strength can be increased through a buttressing technique of folding over the edges of the thin SurgiWrap™ sheet, creating a double layer of SurgiWrap™ sheet of which to suture through.

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

Do Not Reuse
Use by Expiration Date
Lot Number
Sterilized Using Irradiation
Attention, See Instructions for Use
Keep Package Dry
Avoid Extreme Heat



Manufactured by: MAST Bioreabsorbable, Inc.
6749 Top Cam Street, Suite C, San Diego, CA 92121
Phone: (619) 551-0101 or Fax: (619) 550-8860
Visit us online at www.mastbioc.com
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US Patent Nos. 6,531,146 • International Patents Pending
All trademarks and registered trademarks are the property of their respective owners.

K050332

Indications for Use

510(k) Number : K050332

Device Name: Surgi-Wrap MAST Bioresorbable Sheet

Indications for Use:

The Surgi-Wrap MAST Bioresorbable Sheet is to be used wherever temporary wound support is required, to reinforce soft tissues where weakness exists in the urological, gynecological or gastroenterological anatomy, or for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. This includes, but is not limited to the following procedures: pubourethral support and bladder support, urethral and vaginal prolapse repair, colon and rectal prolapse, repair, reconstruction of the pelvic floor and sacral colposuspension. The resorbable Protective Film minimizes tissue attachment to the device in case of direct contact with the viscera. The device is indicated for open and laparoscopic procedures. Laparoscopic procedures are limited to sizes from 0.02mm - 0.2mm in thickness.

Prescription Use X
(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)



Director, Restorative
Biological Devices

K050332

Page 1 of _____

DJA x00138

DJA x00139

Indications for Use

510(k) Number (if known): K072520

Device Name: TephaFLEX® Surgical Film

Indications for Use:

TephaFLEX® Surgical Film is intended for temporary wound support, to reinforce soft tissues where weakness exists, or for the repair of hernia or other fascial defects that require the addition of a reinforcing material to obtain the desired surgical result. The absorbable protective film also may help minimize the potential for tissue attachment to the device in case of direct contact with the viscera.

Prescription Use: X
(21 CFR 801 Subpart D)

AND/OR

Over-The-Counter _____
(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)

Page 1 of 1


(Division Sign-Off)
Division of General Restorative
and Neurological Devices
510(k) Number K072520

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DJA x00140

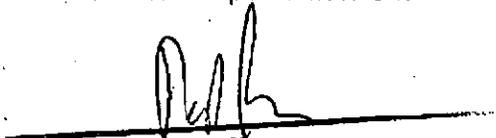
Indications for Use

510(k) Number (if known): Not Assigned

Device Name: TephaFLEX® Surgical Mesh

Indications for Use:

TephaFLEX® Surgical Mesh is intended wherever temporary wound support is required, to reinforce soft tissues where weakness exists or for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. This includes, but is not limited to the following procedures: vaginal prolapse repair, colon and rectal prolapse repair, reconstruction of the pelvic floor and sacral colposuspension.



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

Prescription Use: X AND/OR
(21 CFR 801 Subpart D)

Over-The-Counter _____
510(k) Number (21 CFR 801 Subpart C) L070894

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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DJA x00141

SECTION X

**SUMMARY OF SAFETY AND
EFFECTIVENESS**

115



99 Hayden Avenue
Suite 360
Lexington, MA 02421
tel: (781) 357-1700
fax: (781) 357-1701

Section X Summary of Safety and Effectiveness

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Tepha, Inc. is submitting the following summary of information respecting safety and effectiveness:

Trade Name: TephaFLEX® Surgical Film

Sponsor: Tepha, Inc.
99 Hayden Avenue, Suite 360
Lexington, MA 02421
Telephone: 781.357.1700
Fax: 781.357.1701

Device Classification Name: CFR §878.3300
Surgical Mesh

Classification: According to Section 13 of the Federal Food, Drug and Cosmetic Act, the device classification is Class II, Performance Standards.

Predicate Devices: Tepha, Inc. – TephaFLEX Surgical Film
Tepha, Inc. - TephaFLEX Absorbable Mesh
MAST Biosurgery, Inc. – Surgi-Wrap Film
OsteoBiologics – Immix PlastiFilm

Device Description: TephaFLEX surgical film is intended to be used wherever temporary wound support is required, to reinforce soft tissues where weakness exists in the urological, gynecological, or gastrointestinal anatomy, or for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. The absorbable protective film also may help minimize the potential for tissue attachment to the device in case of direct contact with the viscera.

Safety and Performance: Physical and *in vivo* animal testing was performed on the TephaFLEX surgical film which determined the film to be substantially equivalent to the predicate devices.

Conclusion: Based on the indications for use, technological characteristics, and safety and performance testing, the TephaFLEX surgical film has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

DJA x00005

Transitional Adolescent B (18 <= 21; No special considerations compared to adults => 21 years old)		X X X
Nanotechnology		
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 8K3300 **Class*** II **Product Code** 00D

(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: David Krone PPSB August 7, 2009
 (Branch Chief) (Branch Code) (Date)

Final Review: _____ (Date)
 (Division Director) Dec 11 8/8/09

DCA 200006



DEPARTMENT OF HEALTH AND HUMAN SERVICES M E M O R A N D U M

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

**Premarket Notification [510(k)] Review
Traditional
K091633**

Date:	8/7/09	Office:	ODE
To:	The Record	Division:	DSORD
From:	PL Hudson, Ph.D.		
510(k) Holder:	Tepha, Inc.		
Device Name:	TephaFLEX [®] Surgical Film		
Contact:	Ms. Mary P. LeGraw		
Phone:	781-357-1709		
Fax:	781-357-1701		
Email:	legraw@tepha.com		

Handwritten signature and date: 8/18/09

I. Purpose and Submission Summary

The 510(k) holder would like to introduce TephaFLEX[®] Surgical Film into interstate commerce.

De Novo issue

The sponsor originally gained approval for use of the recombinantly-produced poly-4-hydroxybutyrate (P4HB) via K052225. The subject of the submission, the TephaFLEX suture, was approved as a *de novo* 510(k). Dr. Charles Durfor had written the guidance document to accompany approval of the product. I spoke to him regarding this submission. He asked if a *de novo* had been submitted for the sponsor's original surgical mesh. At the time of the suture submission, the sponsor had also submitted a surgical mesh for review. I asked the sponsor if a *de novo* application for the surgical mesh had been submitted. The sponsor stated that:

(b)(4)

DJA 200007

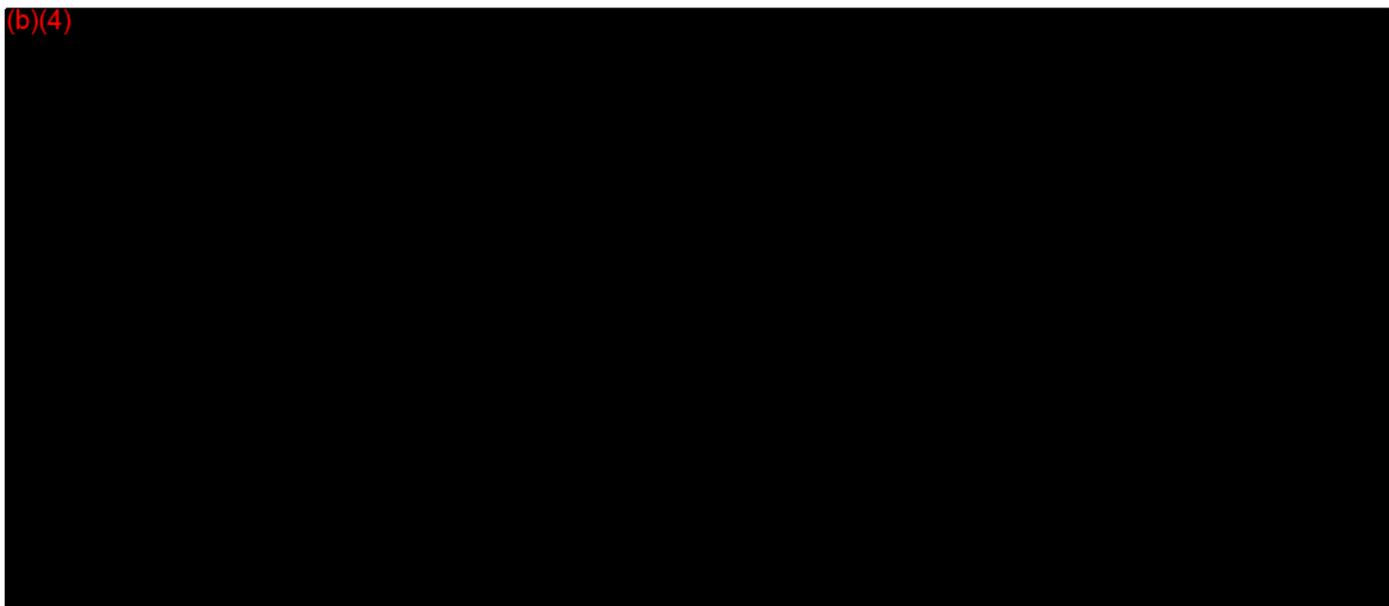
Regards,
Mary

Mary P. LeGraw
Vice President, Regulatory Affairs
Tepha, Inc.
99 Hayden Avenue, Suite 360
Lexington, MA 02421
Telephone: 781.357.1709
Fax: 781.357.1701
Cell: 617.283.6539
E-mail: legraw@tepha.com

I asked Ms. LeGraw to provide documentation to the effect that new submissions would not be required per indication:

Hi Peter,

(b)(4)



Again, I hope this helps.

Regards,
Mary

Mary P. LeGraw
Vice President, Regulatory Affairs
Tepha, Inc.
99 Hayden Avenue, Suite 360
Lexington, MA 02421
Telephone: 781.357.1709
Fax: 781.357.1701
Cell: 617.283.6539
E-mail: legraw@tepha.com

DJA 200008

I spoke to Dr. David Krause and he stated that he believed Mr. Rhodes, branch chief at the time of the decision, indicated to him that additional de novos would not be required per indication. He echoed Ms. LeGraw's statement that the de novo guidance was focused on the material and not the device + indication for use. I checked the guidance (Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Absorbable (b)(4) Surgical Suture Produced by Recombinant DNA Technology to see whether it could be perceived as material-specific. The guidance is specific to use of the material for manufacture of sutures. I reviewed the guidance to discern what controls were specified for ensuring safety of the device/material:

Identified Risk	Recommended Mitigation Measures
Improper Selection and Use	9. Physical and Performance Characteristics 7. Biocompatibility 12. Labeling
Suture Breakage	9. Physical and Performance Characteristics 10. Expiration Dating 7. Biocompatibility
<u>Adverse Tissue Reaction (i.e., irritation, inflammation, immune response)</u>	
Infection	8. Sterility

7. Biocompatibility

We recommend you conduct biocompatibility testing as described in the FDA guidance, **Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing** (the Biocompatibility guidance)⁷. We recommend you select biocompatibility tests appropriate for the duration and level of contact with your device. In addition, we also recommend you evaluate immunogenicity by testing for:

- sensitization
- intracutaneous irritation
- evaluating local tissue response during implantation studies.

We recommend you conduct the tests described above on final finished sterilized sutures. If identical materials and identical material processing are used in a predicate device with the same type and duration of patient contact, you may identify the predicate device in lieu of providing biocompatibility testing.

(b)(4)

I have bolded the relevant concern FDA has had with materials produced via recombinant methods, i.e., that co-purifying proteins may elicit immune responses. FDA in this guidance document recommends standard biocompatibility evaluations for assessment of this potential

DJA 200009

adverse event. The sponsor has done this for the material and the information has supported their contention that the material does not elicit an un-anticipated inflammatory response. The guidance asks the manufacturers to “consider” conducting serological evaluations for immune responses but that falls short of a recommendation or requirement.

Mr. Mark Melkerson stated that the document should be forwarded with a new procode under the surgical mesh regulation, i.e., 21 CFR 878.3300. The new procode name and abbreviation is: OOD, Surgical Film.

II. Administrative Requirements

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

III. 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	

The device is composed of (b)(4) and is identical to the material used in the sponsor’s own predicate device, TephafLEX Film, as cleared via K072520. The predicate device is a solid sheet provided in the following sizes: 50 mm x 70 mm, 100 mm x 130 mm, and 130 mm x 200 mm. The predicate film is approximately 200 microns thick. The subject device of this submission would be available in sizes ranging from 25 mm x 25 mm to 300 mm x 300 mm. The device thickness will range from 60 up to 200 microns.

The sponsor asserts that the new length/width dimensional parameters will not have influence on device safety and effectiveness, and they acknowledge that the change in thickness could have an impact on device performance and so have conducted evaluations to assess for potential strength differences (see preclinical information below).

Product design characteristics

Mesh thickness (b)(4)
 Weave characteristics solid sheet – not a woven mesh
 Pore size no pores

Device density
Device stiffness

(b)(4)
horizontal: (b)(4) vertical: (b)(4)
b

IV. Indications for Use

[The device] is intended to be used wherever temporary wound support is required, to reinforce soft tissues where weakness exists in the urological, gynecological, or gastrointestinal anatomy, or for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. The absorbable protective film also may help minimize the potential for tissue attachment to the device in case of direct contact with the viscera.

V. Predicate Device Comparison

The sponsor has cited the following predicates for technological characteristics and for comparison of intended uses:

- K072520, TephaFLEX Surgical Film
- K070894, TephaFLEX Absorbable Mesh
- K031955, K050332, MAST Biosurgery, Inc., Surgi-Wrap Film
- K033671, W.L. Gore, Gore Bioabsorbable Mesh
- K032673, OsteoBiologics, Inc., Immix PlastiFilm

The MAST Biosurgery indication for use statement says:

- [The device] is intended to be used wherever temporary wound support is required, to reinforce soft tissues where weakness exists *in the urological, gynecological, or gastrointestinal anatomy*, or for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. This includes, but is not limited to the following procedures: pubourethral support and bladder support, urethral and vaginal prolapse repair, colon and rectal prolapse, repair, reconstruction of the pelvic floor and sacral colposuspension. The resorbable protective film minimizes tissue attachment to the device in case of direct contract with the viscera. The device is indicated for open and laparoscopic procedures. Laparoscopic procedures are limited to sizes from 0.02 mm – 0.2 mm in thickness.

The sponsor's own predicate device (K072520) states:

- [The device] is intended to be used wherever temporary wound support is required, to reinforce soft tissues where weakness exists, or for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. *The absorbable protective film also may help minimize the potential for tissue attachment to the device in case of direct contact with the viscera.*

The proposed indications for use are equivalent to those of the sponsor's own predicate surgical mesh IFU's and other predicate surgical mesh IFU's. The subject IFU now contains

DJA 200011

reference to use of the device in the urological, gynecological, or gastrointestinal anatomy which is cited in the MAST Biosurgery indication for use statement. Hernia repair may involve these tissues, in general, and the reference is non-specific. Based on the animal performance, biodegradation and physical strength evaluations identified below, the subject device is stronger than the MAST device and so the addition of these general references does not raise safety or effectiveness concerns. In addition, the IFU specifies that the absorbable protective film also may help minimize the potential for tissue attachment to the device in case of direct contact with the viscera. Dr. Krause cautioned against the promotion of the device as an adhesion barrier. The statement implies some potential for minimizing adhesions but stops short of saying that the product is an adhesion barrier. I called the company to make sure that they understand FDA's concern regarding this issue.

On July 22, 2009 I spoke with Ms. Mary LeGraw regarding the promotion of the device as an adhesion barrier. I stated that FDA does not believe that the information provided in the application supports the advertisement of the device as an adhesion barrier. **Ms. LeGraw stated that she, and the company, were very sensitive to this issue as well and that they would not be marketing the product in this manner. I told Ms. LeGraw that I would document our discussion in the 510(k) review memo, i.e., that FDA and the sponsor were on the same page regarding this issue.**

With regard to the technology/chemistry of the product, the device is identical, chemically to its' own predicate product albeit it is a (b) (4) version, i.e., (b)(4) (b) (4). Therefore, any biodegradation/chemical byproduct issues regarding the resorption of the device would be lessened rather than increased or to pose new concerns – that is there would be less of it to resorb. Legally marketed resorbable surgical meshes have the following thicknesses and resorption profiles:

Mesh	Thickness (µm)	Resorption time (complete)
TephaFLEX Film (K072520)	200	12 months
TephaFLEX Surgical Mesh (K070894)	580	12 months
SurgiWrap	20-100	12-18 months
PlastiFilm	50-300	60-90 days

The complete resorption of the subject device is stated to be 12 months however, it is unclear what information is referenced to make that statement, i.e., are they basing it on the original TephaFLEX clearances? Mechanically, the preclinical information below, i.e., before and after implantation shows that the product is substantially equivalent to 2 other surgical mesh products, i.e., SurgiWrap and PlastiFilm. While this thinner version of TephaFLEX is not as strong as the sponsor's 200 micron version, manufacturers are marketing various strength surgical meshes for various repair uses and needs. The indications for use and the device technology are substantially equivalent to predicate surgical mesh products.

VI. Labeling

The sponsor's product label is similar to their previously cleared Surgical Mesh label. However, there are 2 differences:

DJA X00012

- The label now contains the following statement: "The safety and effectiveness of [the device] used to reduce the incidence, extent and severity of postoperative adhesions have not been established in prospective, randomized clinical trials."
- A table presenting the burst strength determinations of the subject device and the sponsor's predicate surgical mesh over time of implantation was provided.

The statement regarding the reduction of adhesion incidence, etc... implies that the device may function in this manner. Therefore, I believe it should be omitted. The table of strength information is important but a description of how the determinations were done, i.e., implantation within subcutaneous tissue, etc... should be provided so that users understand the strength determinations were not done via an abdominal defect, or hernia repair model.

With respect to the adhesion incidence, etc... statement, the sponsor provided the previously cleared product label which contains the same statement. The sponsor noted that the statement was requested by an FDA reviewer (Ms. Nada Hanafi). I discussed the issue with Dr. David Krause, branch chief of Plastic and Reconstructive Surgery. Dr. Krause stated that since FDA asked for the statement, and since it had been cleared, he believed the statement should stay in the label. To address the implantation study findings, the sponsor provided a revised product label containing the following statement on top of the table:

Subcutaneous implantation studies performed in a rabbit model indicate the following strength retention over time:

I believe this adequately addresses the concern.

VII. Sterilization/Shelf Life/Reuse

Packaging

(b)(4)

(b)(4) Package integrity testing will be in compliance with ANSI/AAMI/ISO 11607-1:2006: Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems.

Sterilization

(b)(4)

Pyrogenicity:

(b)(4)

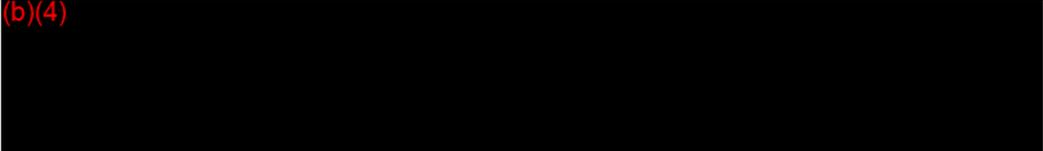
(b)(4) The sponsor cites the 0.5 EU/mL recommended medical device implant endotoxin specification (non-

neural).

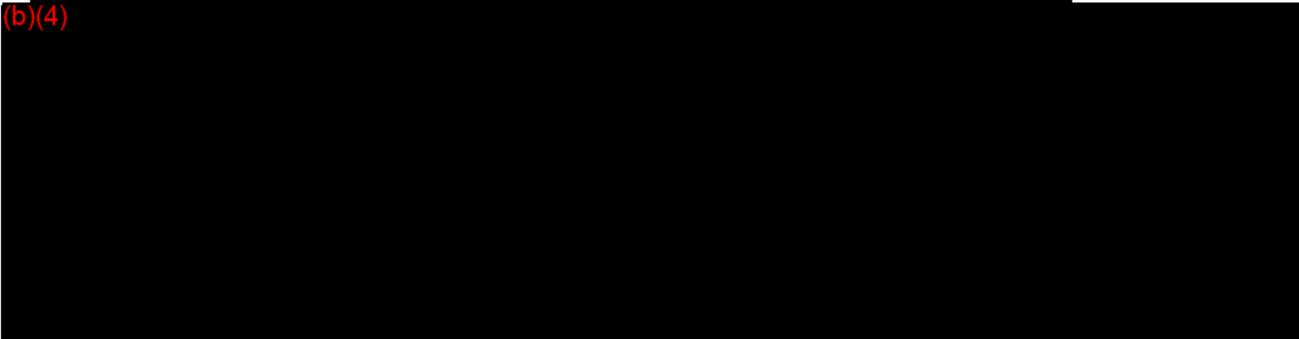
VIII. Biocompatibility

Since the material itself has not been changed, chemically, the sponsor cites the biocompatibility previously conducted. They have provided summaries of the results of those tests. The assessments conducted included the following subset of particular importance:

(b)(4)

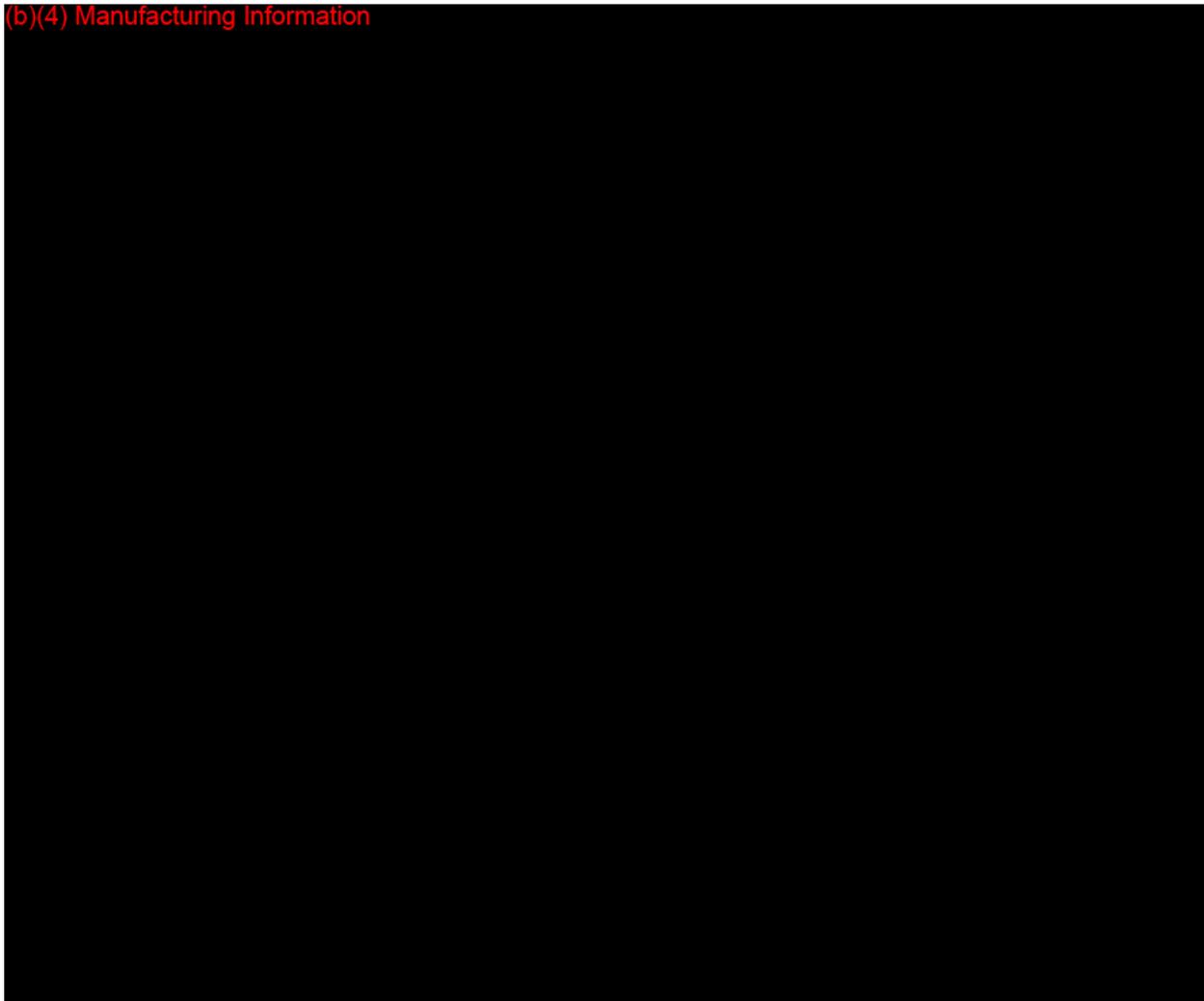
A large black rectangular redaction box covering several lines of text.

(b)(4)

A large black rectangular redaction box covering the majority of the lower half of the page.

DJA 200014

(b)(4) Manufacturing Information



I believe this information reasonably addresses the potential mutagenicity of the chemical. Therefore, the biocompatibility of the device has been adequately established.

IX. Software – N/A

Version:		
Level of Concern:		
	Yes	No
Software description:		
Device Hazard Analysis:		
Software Requirements Specifications:		
Architecture Design Chart:		
Design Specifications:		
Traceability Analysis/Matrix:		
Development:		
Verification & Validation Testing:		

DJA 200015

Revision level history:		
Unresolved anomalies:		

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety – N/A

XI. Performance Testing – Bench

(b)(4)

Functional/mechanical testing

Test	Device	Values
------	--------	--------

Burst strength	(b)(4)	
Suture pull-out strength		
Tensile strength		
Tear resistance		

The information demonstrates that the subject device is equivalent in strength, if not significantly stronger than, a predicate surgical mesh indicated for the same intended uses.

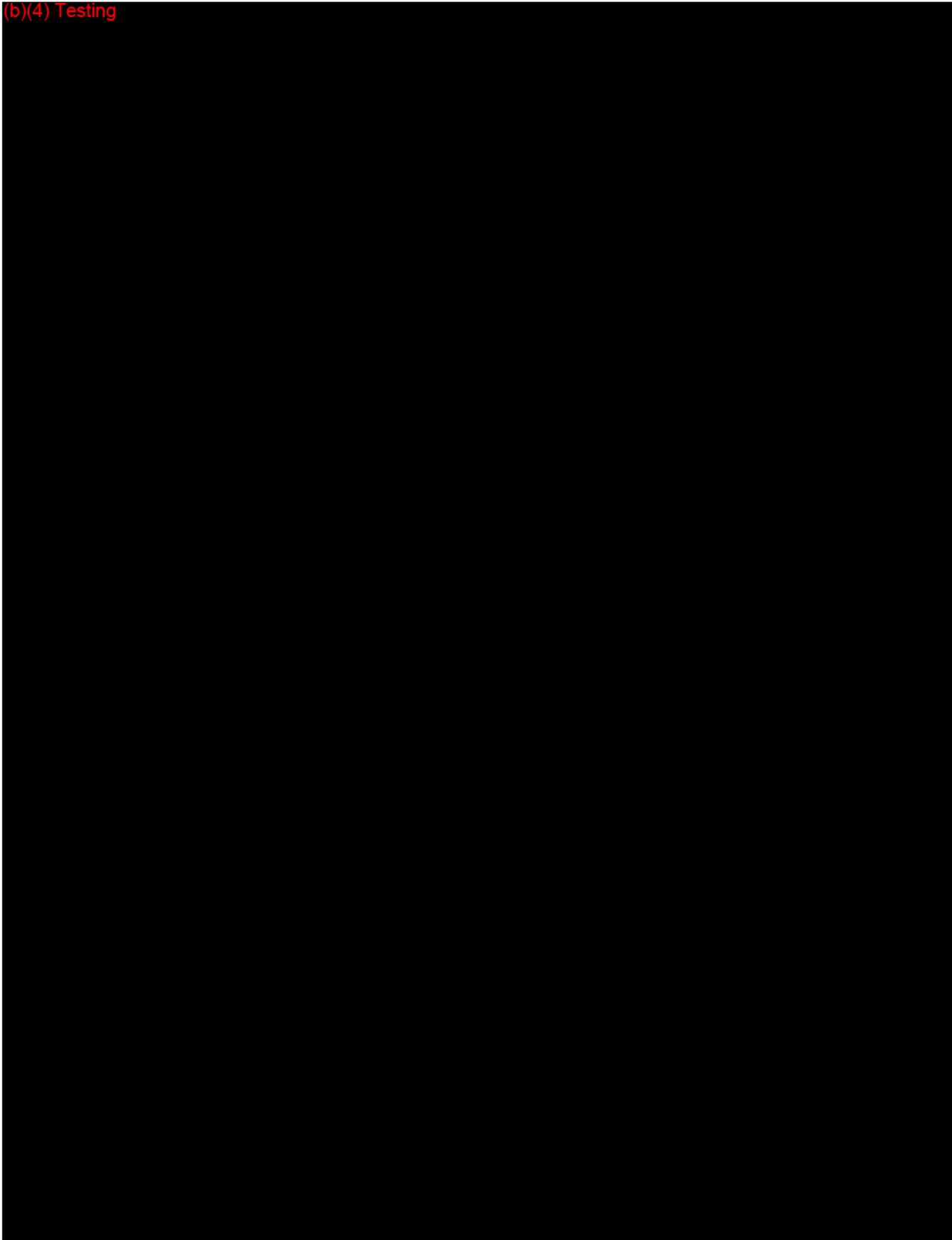
XII. Performance Testing – Animal

The sponsor conducted an in vivo animal model evaluation to assess the performance of the

(b)(4) thick subject mesh. The animal model was a (b)(4) 1
(b)(4)

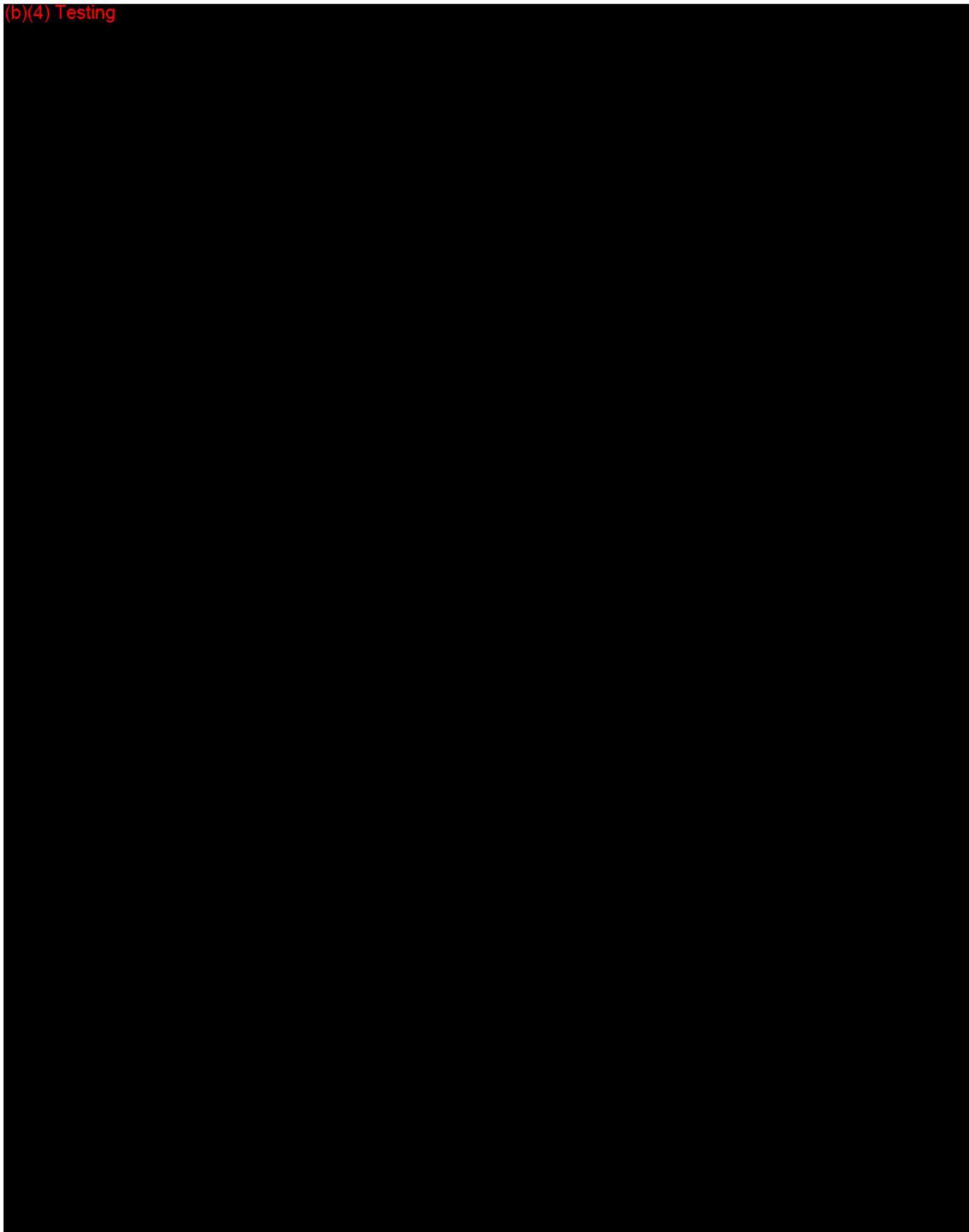
DJA 200016

(b)(4) Testing

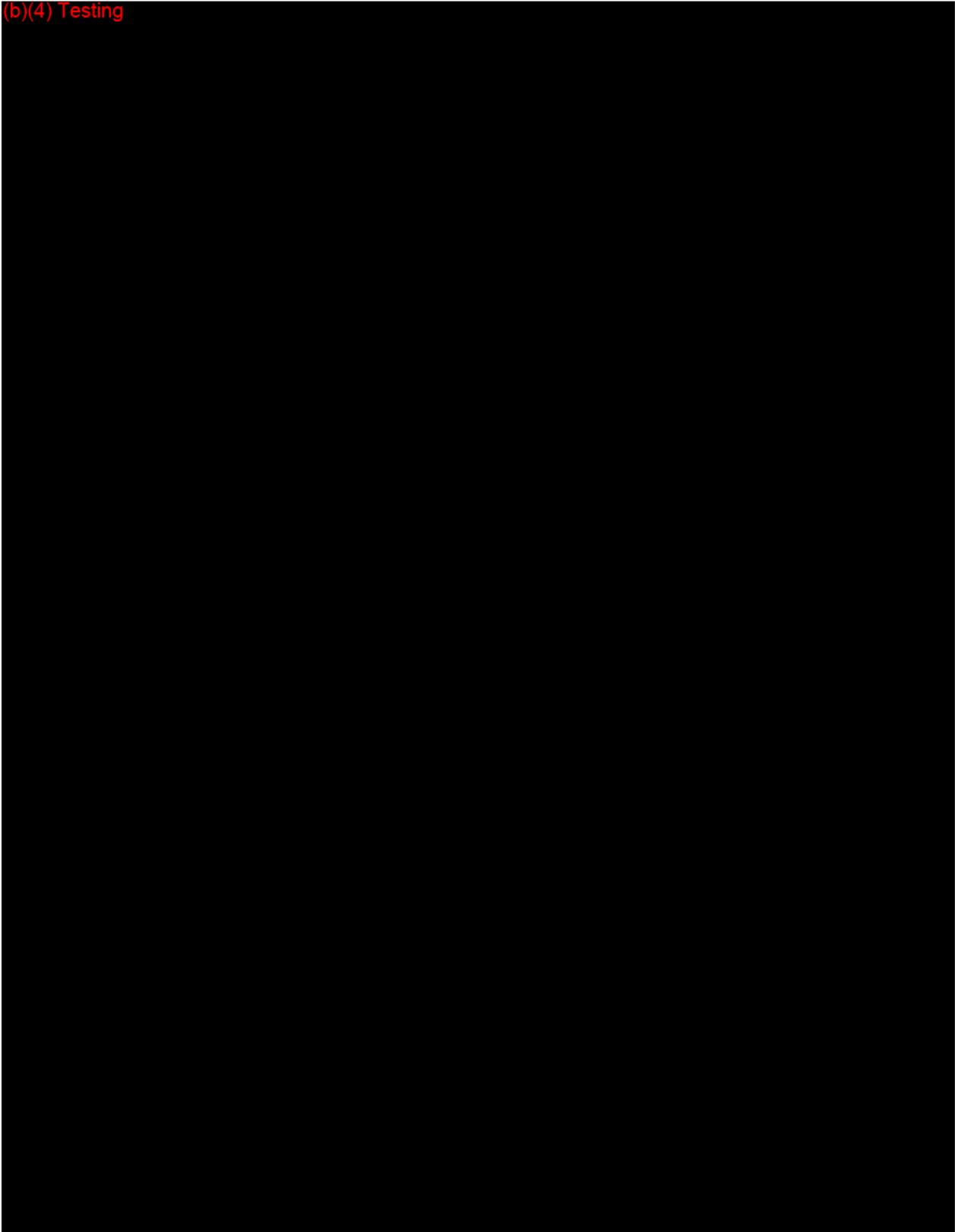


DJA x00017

(b)(4) Testing



(b)(4) Testing



XIII. Performance Testing – Clinical – None provided

DJA x00018

DJA X00019

XIV. 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?		X	If YES = Stop NSE
3. Same Technological Characteristics?	X		If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 6
5. Descriptive Characteristics Precise Enough?	X		If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NSE
7. Accepted Scientific Methods Exist?			If NO = Stop NSE
8. Performance Data Available?			If NO = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

Note: See

http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue: the subject device is identical, chemically, to the sponsor's own predicate product; information demonstrating technological and strength equivalence was provided.
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XV. Deficiencies

I asked the sponsor to revise their product label to specify how the data in the table regarding burst strength over time was collected.

XVI. Contact History

July 21, 2009 phone and email

XVII. Recommendation

Regulation Number: 21 CFR 878.3300

Regulation Name: Surgical Film

Regulatory Class: II

Product Code: OOD

[Signature]

Reviewer

8/7/09

Date

David Krone *I concur*

Branch Chief

8/7/2009

Date

*Additionally,
we will be issuing
correction letters for
this sponsor's previously cleared
510(k)s for this mesh assigning
the new product code OOD.*

DJA x00020

Krause, David

From: Stuart, Julie (Brandi)
Sent: Friday, August 07, 2009 7:30 AM
To: Hudson, Peter
Cc: Krause, David
Subject: FW: New Product Code OOD Created

Hi Peter

Here is your new product code, please let me know if you need anything else.

If the product code awaiting Mark's approval expires you will need to create a new product code request, that is not a big deal really I just wanted to give you a heads up on the process.

Let me know if you need anything else.

Brandi

Julie "Brandi" Stuart
 Consumer Safety Officer
 Center Product Code Coordinator

And in the end, it's not the years in your life that count. It's the life in your years. ~ Abraham Lincoln

From: CDRH Center Tracking System [mailto:cdrhcts@cdrh.fda.gov]
Sent: Friday, August 07, 2009 7:29 AM
To: CDRH New Device Request Approval
Subject: New Product Code OOD Created

August 7, 2009

A new product code has been added to the CDRH Product Code Database. Below you will find detailed information concerning this new product code for your information and review.

Important: Any product code marked as not releasable (please see below) must not be released in accordance with 21 CFR 807.95, 21 CFR 814.9, 21 CFR 814.122 and 21 CFR 812.38.

NEW PRODUCT CODE:	OOD
RELEASABLE:	Yes
CTS DOCUMENT NUMBER:	DR090088
REASON FOR NEW	Premarket Notification (510(k))

DJA x00022

PRODUCT CODE:

DEVICE / PRODUCT NAME: Surgical film

REVIEW PANEL: General And Plastic Surgery

CLASS: 2

EXEMPT STATUS: Non-Exempt

REGULATION NUMBER: 878.3300

DEFINITION: To be implanted to reinforce soft tissue or bone where weakness exists. Intended to be used wherever temporary wound support is required, to reinforce soft tissues where weakness exists in the urological, gynecological, or gastrointestinal anatomy, or for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. The absorbable protective film also may help minimize the potential for tissue attachment to the device in case of direct contact with the viscera.

MAY PROCEED: 80%

Important: If this new product code impacts any recognized standards, please e-mail Gail Strieter of OSEL or call her at 301-796-3949. If this new product code impacts any current guidance or guidance undergoing the GGP process, please contact your GGP representative as well. This will ensure that the appropriate databases are updated and accurate information is made available on the web.

If you have any questions or comments please e-mail Julie "Brandi" Stuart or call her at 301-796-6573.

This is an automated e-mail. Please do not reply to this message.