



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (kml)
FOLDER: K071371 - 283 pages
COMPANY: TYCO HEALTHCARE GROUP, LP (TYCOHEALGROULP)
PRODUCT: DRESSING, WOUND, DRUG (FRO)
SUMMARY: Product: COPA AMD ANTIMICROBIAL WOUND DRESSING

DATE REQUESTED: Mar 22, 2016

DATE PRINTED: Mar 22, 2016

Note: Printed



510(k) Premarket Notification
COPA AMD Antimicrobial Wound Dressing

K071371
page 1 of 2

Section B – 510(K) Summary

**Date Summary
Was Prepared:** May 11, 2007

**Submitter's
Information:** Kendall
a Division of Tyco Healthcare Group LP
15 Hampshire Street
Mansfield, MA 02048
Phone: 508-261-8000
Fax: 508-261-6644

Contact: James Welsh
VP, Regulatory Affairs
Kendall
a Division of Tyco Healthcare Group LP
Telephone: 508-261-8532
Fax: 508-261-8461

NOV 19 2007

**Device Trade
Name:** COPA AMD Antimicrobial Wound Dressing

**Device Common
Name:** Wound Dressing, Antimicrobial

Classification Panel: General and Plastic Surgery

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

The COPA AMD antimicrobial wound dressing is substantially equivalent to the existing COPA (Curafoam) polyurethane foam wound dressings in intended use, materials, physical characteristics, and performance characteristics. The modification attributed to the predicate device is the addition of PHMB antimicrobial agent to prevent bacterial penetration and colonization of the dressing.

Substantial equivalence is also claimed to Kerlix AMD and Excilon AMD, absorbent wound dressings which contain PHBM antimicrobial agent to prevent bacterial penetration and colonization of the dressing.

510(k) Premarket Notification
COPA AMD Antimicrobial Wound Dressing

Section B – 510(K) Summary

Device Description:

COPA AMD is a hydrophilic polyurethane foam that is impregnated with Polyhexamethylene Biguanide Hydrochloride (PHMB), an antimicrobial agent that protects the dressing from bacterial penetration and colonization.

Intended Use:

COPA AMD dressings are indicated for use in management of post-surgical incisions, pressure sores, venous stasis ulcers, diabetic ulcers, donor sites, abrasions, lacerations, 1st and 2nd degree burns, dermatologic disorders, other wounds inflicted by trauma and, as a secondary dressing or cover dressing for packed wounds.

Performance Data: Performance data submitted in support of this 510k included in-vitro and animal testing.

Broad spectrum activity was demonstrated against 6 organisms including gram positive, gram negative, and fungal types. Total kill was achieved for 7 consecutive days, with a daily challenge of >6 log of each organism:

- P. aeruginosa
- E. coli
- C. albicans
- S. epidermidis
- S. aureus
- E. faecalis



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 19 2007

Tyco Healthcare LLP
% Mr. James Welsh
VP, Regulatory Affairs
15 Hampshire Street
Mansfield, Massachusetts 02048

Re: K071371

Trade/Device Name: COPA AMD antimicrobial wound dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 2, 2007
Received: November 7, 2007

Dear Mr. Welsh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

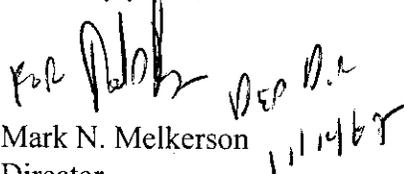
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

Page 2 – Mr. James Welsh

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,


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

Enclosure

Indications for Use Statement

510(k) number: K071371

Device Name:

COPA AMD antimicrobial wound dressing

Indications for Use:

COPA AMD dressings are indicated for use in management of post-surgical incisions, pressure sores, venous stasis ulcers, diabetic ulcers, donor sites, abrasions, lacerations, 1st and 2nd degree burns, dermatologic disorders, other wounds inflicted by trauma and, as a secondary dressing or cover dressing for packed wounds.

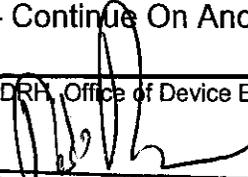
Prescription Use x
(Part 21 CFR 801 Subpart D)

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 CDRL, Office of Device Evaluation (ODE)



(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K071371



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Tyco Healthcare LLP
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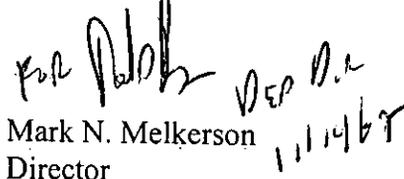
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Sincerely yours,


Mark N. Melkerson
Director

Division of General, Restorative
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Office of Device Evaluation
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Radiological Health

Enclosure



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Tyco Healthcare Group, LP
% Mr. James Welsh
Vice President, Regulatory Affairs
15 Hampshire Street
Mansfield, Massachusetts 02048

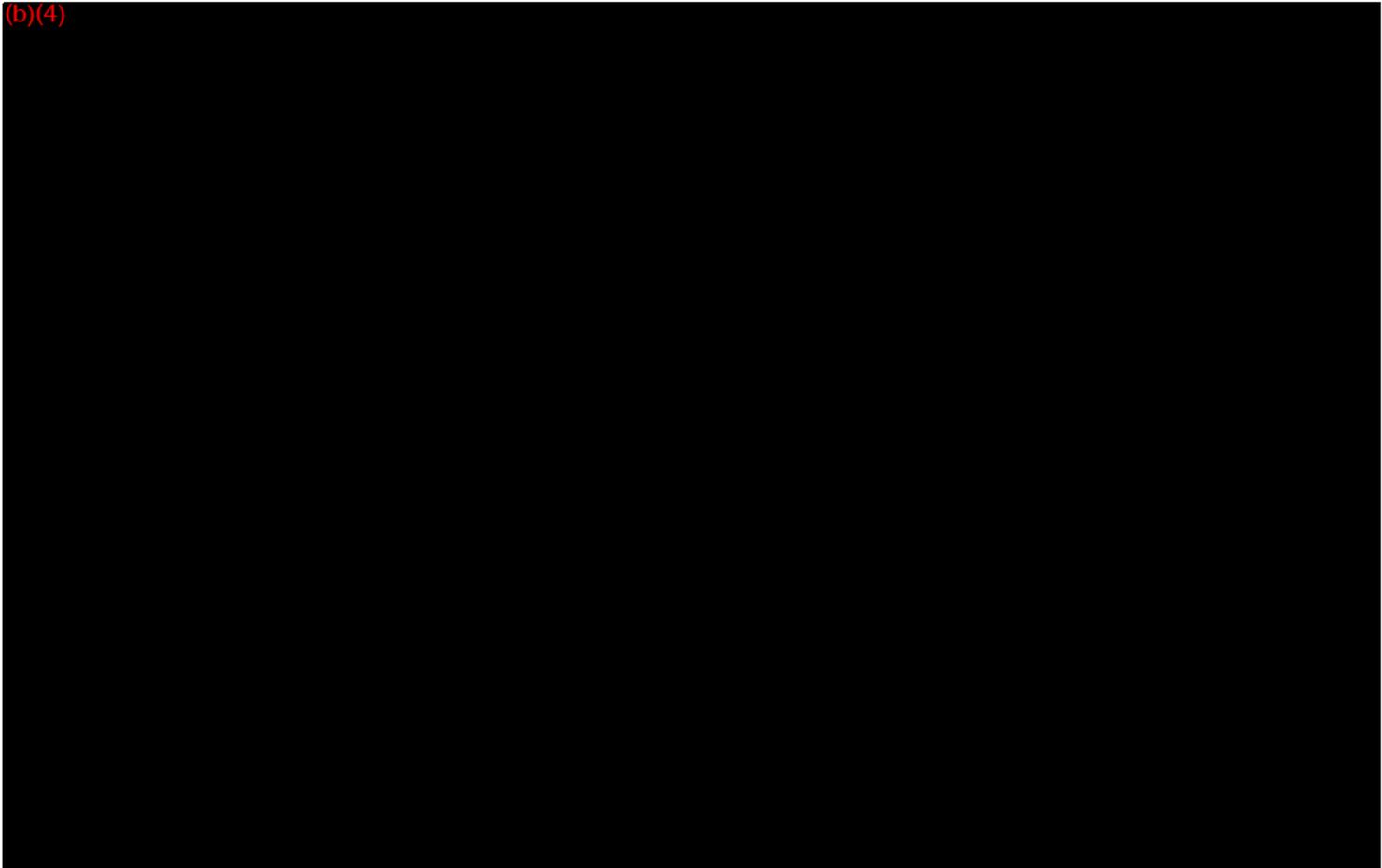
OCT - 3 2007

Re: K071371/S1
Trade Name: COPA AMD Antimicrobial Foam Wound Dressing
Dated: September 7, 2007
Received: September 11, 2007

Dear Mr. Welsh:

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

(b)(4)



(b)(4)

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

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

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

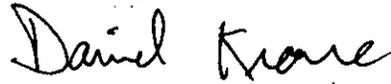
If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. Please note our guidance document entitled, "Guidance for Industry and FDA Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>

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

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

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

Sincerely yours,



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

OCT - 3 2007

Tyco Healthcare Group, LP
% Mr. James Welsh
Vice President, Regulatory Affairs
15 Hampshire Street
Mansfield, Massachusetts 02048

Re: K071371/S1

Trade Name: COPA AMD Antimicrobial Foam Wound Dressing

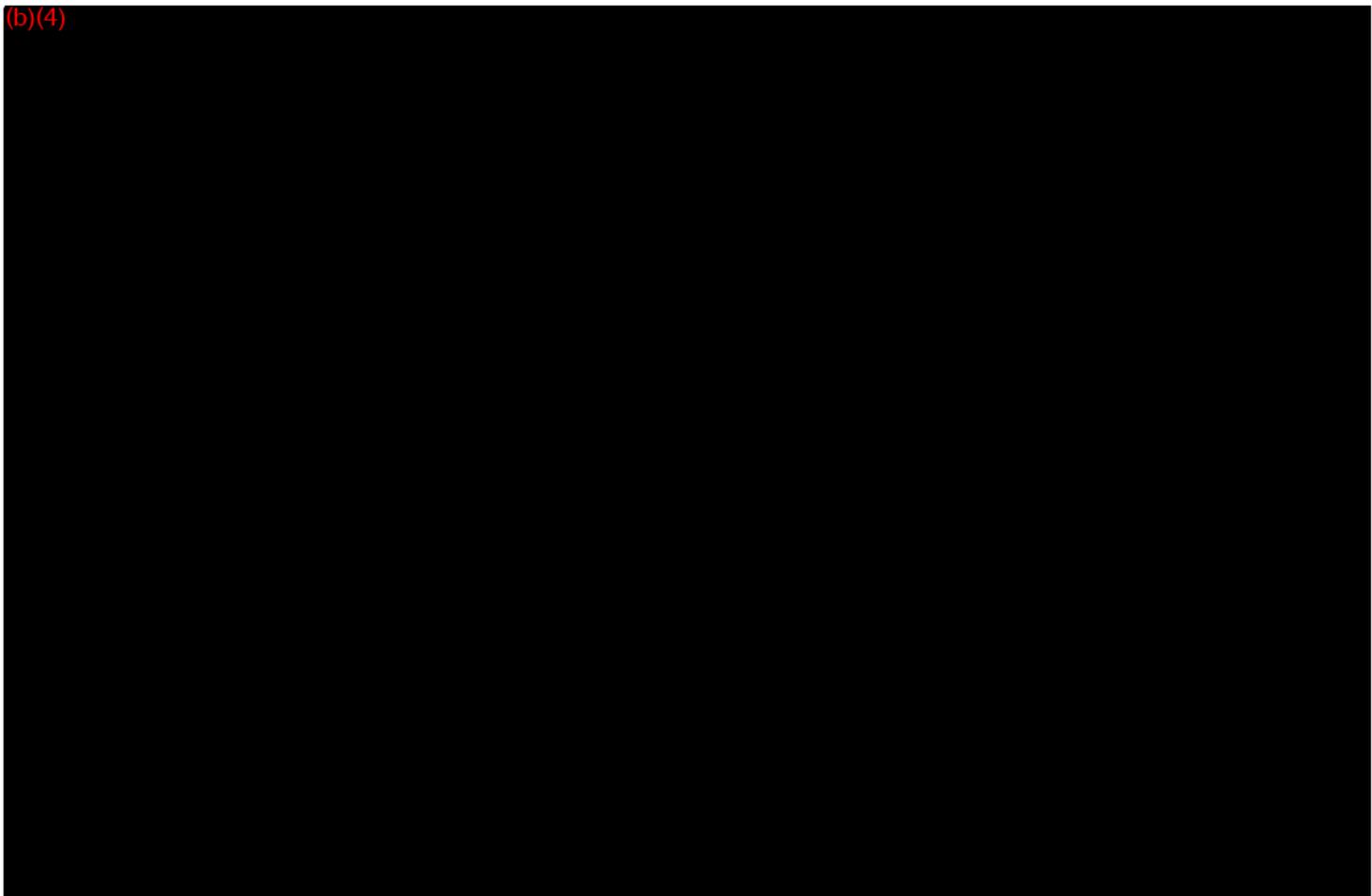
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Page 3 - Mr. James Welsh

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Sincerely yours,

Mark Melkerson
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Center for Devices and
Radiological Health

FILE
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OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
2-44	Sam Arepalli	10/31/07						
2-410	Krause	10/31/07						

Page 4 - Mr. James Welsh

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ- 410 (DGRND/PRSB)
D.O.

f/t:SArepalli:tlm:10-2-07



JUN 11 2007

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Tyco Healthcare Group, LP
% Mr. James Welsh
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15 Hampshire Street
Mansfield, Massachusetts 02048

Re: K071371

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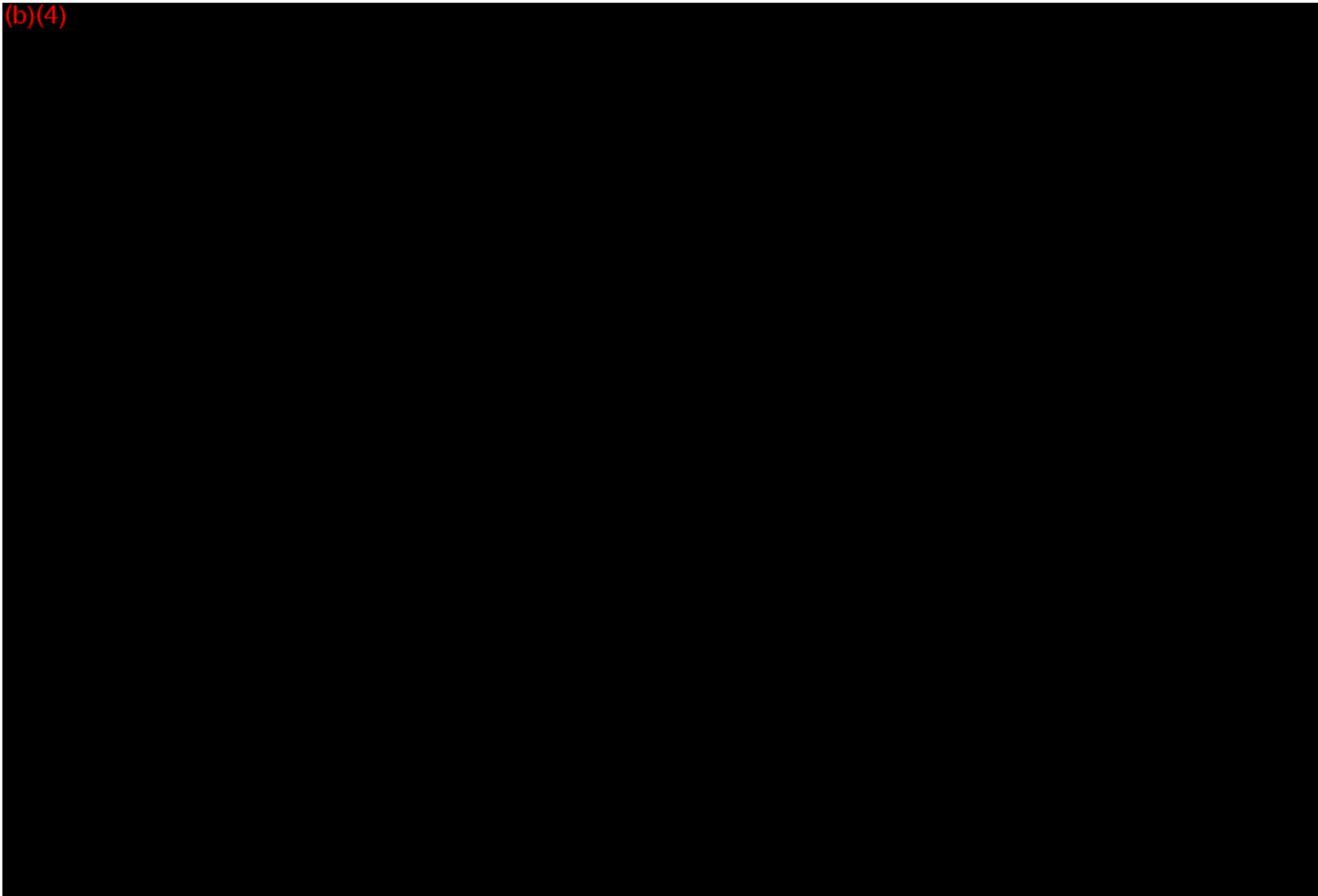
Dated: May 11, 2007

Received: May 16, 2007

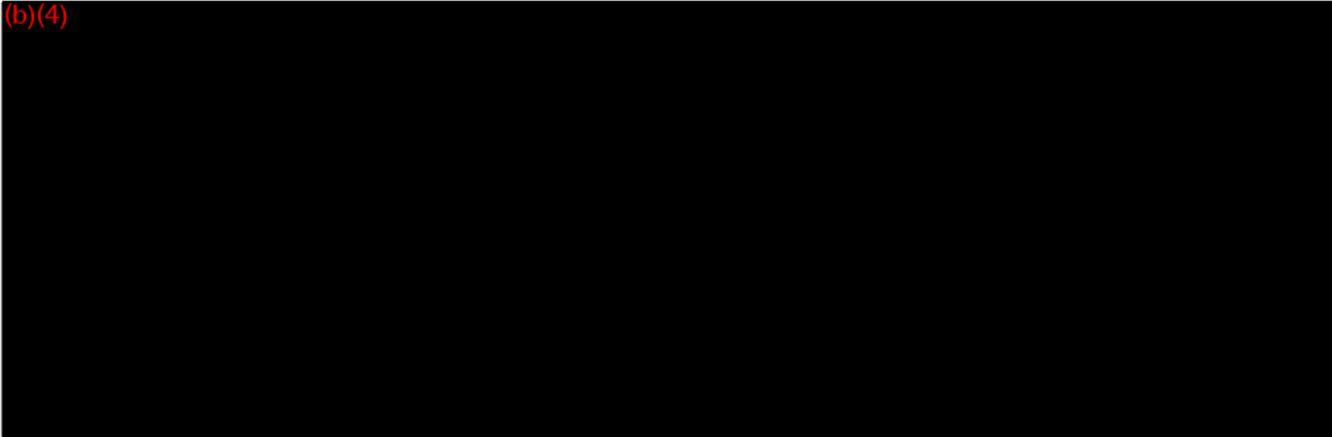
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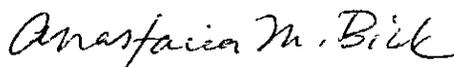
Page 3 - Mr. James Welsh

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Sincerely yours,


for Mark N. Melkerson
Director
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JUN 11 2007

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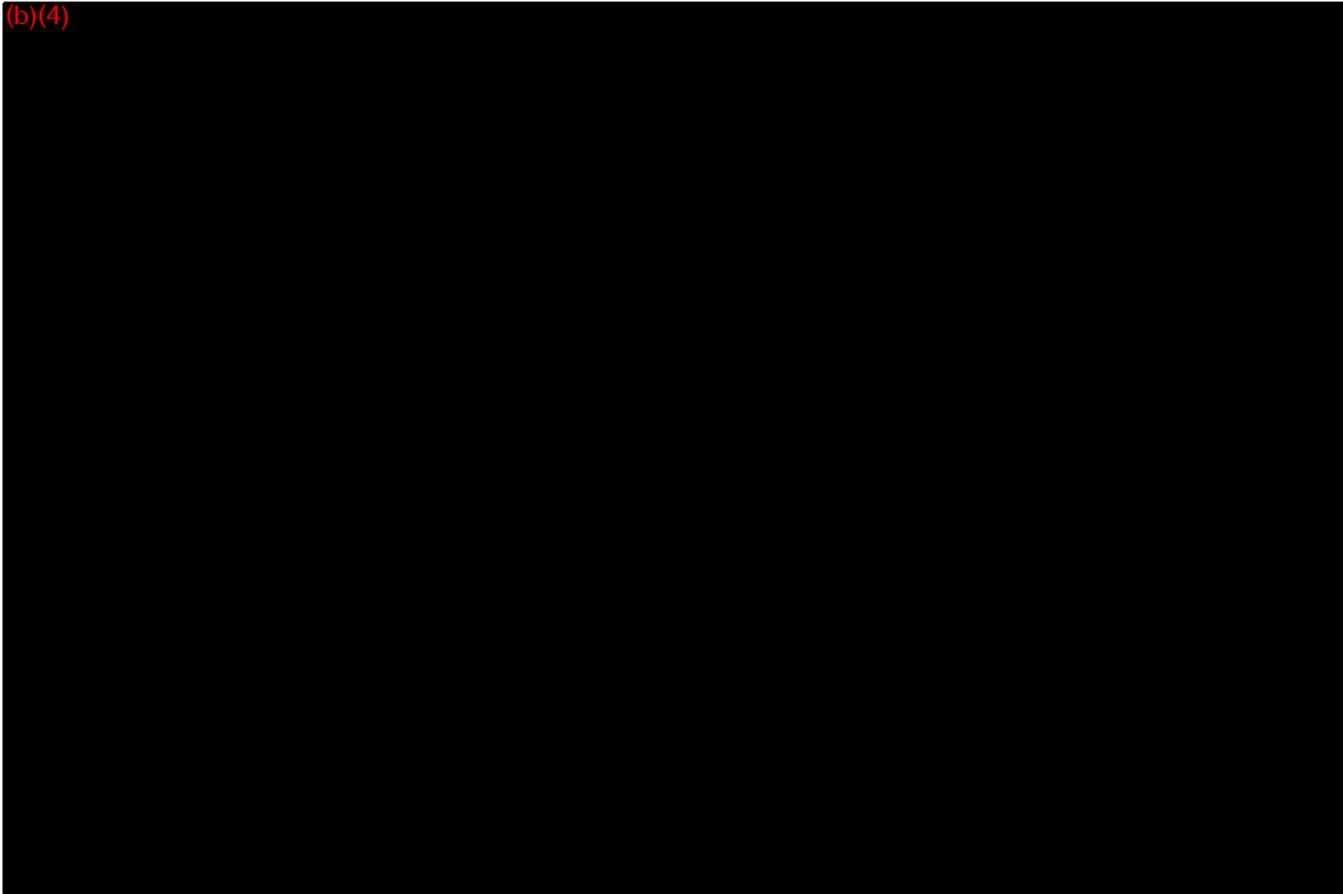
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

FILE
COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
2-410	S. Arepalli	9/14/03						
2-410	A. Bill	6/11/03						

Page 4 - Mr. James Welsh

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ- 410 Division
D.O.
f/t:SArepalli:tlm:6-8-07

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

May 17, 2007

TYCO HEALTHCARE GROUP, LP
15 HAMPSHIRE ST.
MANSFIELD, MA 02048
ATTN: JAMES WALSH

510(k) Number: K071371
Received: 16-MAY-2007
Product: COPA AMD
ANTIMICROBIAL WOUND
DRESSING

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

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

Please note the following documents as they relate to 510(k) review:
1) Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act (MDUFMA). Please review this document at www.fda.gov/cdrh/mdufma/guidance/1219.html.
2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).
3) Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

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

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

Sincerely yours,

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

tyco

Healthcare

endall

K071371
15 Hampshire Street
Mansfield, MA 02048

Tel: 508-261-8000
www.kendallhq.com

FDA CDRH DMC

MAY 16 2007

RECEIVED

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

May 11, 2007

RE: 510(k) Premarket Notification for COPA AMD Antimicrobial Foam Wound Dressing

Dear Sir / Madam:

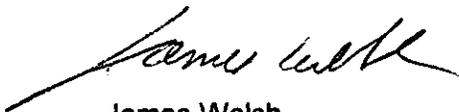
Pursuant to the Section 510(k) of the Food, Drug and Cosmetic Act, as amended, Tyco Healthcare/Kendall respectfully submits the premarket notification for the above subject product. Two copies of this premarket notification are enclosed.

A 510(k) Summary is provided in Section B of this premarket notification.

Tyco Healthcare/Kendall considers its intent to market this device to be confidential information, therefore exempt from public disclosure. Portions of this submission may be considered to be trade secrets and / or confidential information. These sections, if any, have been marked as such, and should be treated as confidential even after marketing commences.

Please contact the undersigned at (508) 261-8532 should you have any question. We appreciate in advance for your consideration of our application and look forward to an expeditious review and approval.

Sincerely,



James Welsh
Vice President, Regulatory Affairs
Tyco Healthcare/Kendall

Enclosure

K8
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Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.	
A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:			
<ol style="list-style-type: none"> 1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent. 2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check. 3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (Note: In no case should payment be submitted with the application.) 4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.) 5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer. 6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center. 			
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) TYCO HEALTHCARE LLP 15 HAMPSHIRE STREET MANSFIELD MA 02048 US		2. CONTACT NAME James Welsh 2.1 E-MAIL ADDRESS jim.welsh@tycohealthcare.com 2.2 TELEPHONE NUMBER (include Area code) 508-2618532 2.3 FACSIMILE (FAX) NUMBER (Include Area code) null-null	
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)(4)			
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma)			
Select an application type:		3.1 Select one of the types below	
<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party		<input checked="" type="checkbox"/> Original Application	
<input type="checkbox"/> Biologics License Application (BLA)		Supplement Types:	
<input type="checkbox"/> Premarket Approval Application (PMA)		<input type="checkbox"/> Efficacy (BLA)	
<input type="checkbox"/> Modular PMA		<input type="checkbox"/> Panel Track (PMA, PMR, PDP)	
<input type="checkbox"/> Product Development Protocol (PDP)		<input type="checkbox"/> Real-Time (PMA, PMR, PDP)	
<input type="checkbox"/> Premarket Report (PMR)		<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. 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, parents, and partner firms		<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population	
<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 application is submitted by a state or federal government entity for a device that is not to be distributed commercially	
6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)			
<input type="checkbox"/> YES		<input checked="" type="checkbox"/> NO	
7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b)(4)			
25-Apr-2007			

Form FDA 3601 (01/2007)

["Close Window"](#) [Print Cover sheet](#)

510(K) PREMARKET NOTIFICATION

**COPA AMD
ANTIMICROBIAL FOAM WOUND DRESSING**

May 11, 2007

510(k) Premarket Notification
COPA AMD Antimicrobial Wound Dressing**Table of Contents**

Section	Content	Page Number
	Cover Sheet Truthful and Accurate Statement	002-008
A	General Device Summary	009-011
B	510(k) Summary	012-013
C	Labels and Labeling	014-034
D	Device Description	035-038
E	Descriptive Comparison to Legally Marketed Devices	039-040
F	Summary of Design Control Activities	041-043
G	Sterilization Information	044
Appendix 1	Indications for Use Statement	045
Appendix 2	Biocompatibility Reports	046-077
Appendix 3	Design FMEA	078-083
Appendix 4	Toxicology Assessment of PHMB use in wound dressings	084-105
Appendix 5	Antimicrobial Efficacy Study	106-136

Date of Submission: 5/11/07
 User Fee Payment ID Number: (b)(4)
 FDA Submission Document Number (if known):

SECTION A TYPE OF SUBMISSION

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

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name Tyco Healthcare LLP		Establishment Registration Number (if known) 1282497	
Division Name (if applicable) Kendall		Phone Number (including area code) (508) 261-8532	
Street Address 15 Hampshire Street		FAX Number (including area code) (508) 261-8461	
City Mansfield	State / Province MA	ZIP/Postal Code 02048	Country USA
Contact Name James Welsh			
Contact Title VP, Regulatory Affairs		Contact E-mail Address jim.welsh@tycohealthcare.com	

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

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

002 ~~001~~
142

SECTION D1

REASON FOR APPLICATION - PMA, PDP, OR HDE

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

SECTION D2

REASON FOR APPLICATION - IDE

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

SECTION D3

REASON FOR SUBMISSION - 510(k)

<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
<input type="checkbox"/> Other Reason (specify):		

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143

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

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

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

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K946269	1	COPA (Curafoam)	1	Tyco Healthcare LLP
2	K990530	2	Kerlix AMD	2	Tyco Healthcare LLP
3	K011941	3	Excilon AMD	3	Tyco Healthcare LLP
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification
 NAD – Occlusive wound dressing

	Trade or Proprietary or Model Name for This Device		Model Number
1	COPA AMD	1	Multiple sizes
2		2	
3		3	
4		4	
5		5	

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

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

Data Included in Submission
 Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code NAD	C.F.R. Section (if applicable) 878.4020	Device Class <input checked="" type="checkbox"/> Class I <input type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel General and Plastic Surgery		

Indications (from labeling)
 Management of post-surgical incisions, pressure sores, venous stasis ulcers, diabetic ulcers, donor sites, abrasions, lacerations, 1st and 2nd degree burns, dermatologic disorders, other wounds inflicted by trauma and, as a secondary dressing or cover dressing for packed wounds. COPA AMD dressings may be used on infected wounds as part of the overall medical treatment where a foam dressing is indicated for protection of the wound. The barrier function of this wound dressing may help reduce wound infections.

004
144

SECTION D1

REASON FOR APPLICATION - PMA, PDP, OR HDE

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

SECTION D2

REASON FOR APPLICATION - IDE

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

SECTION D3

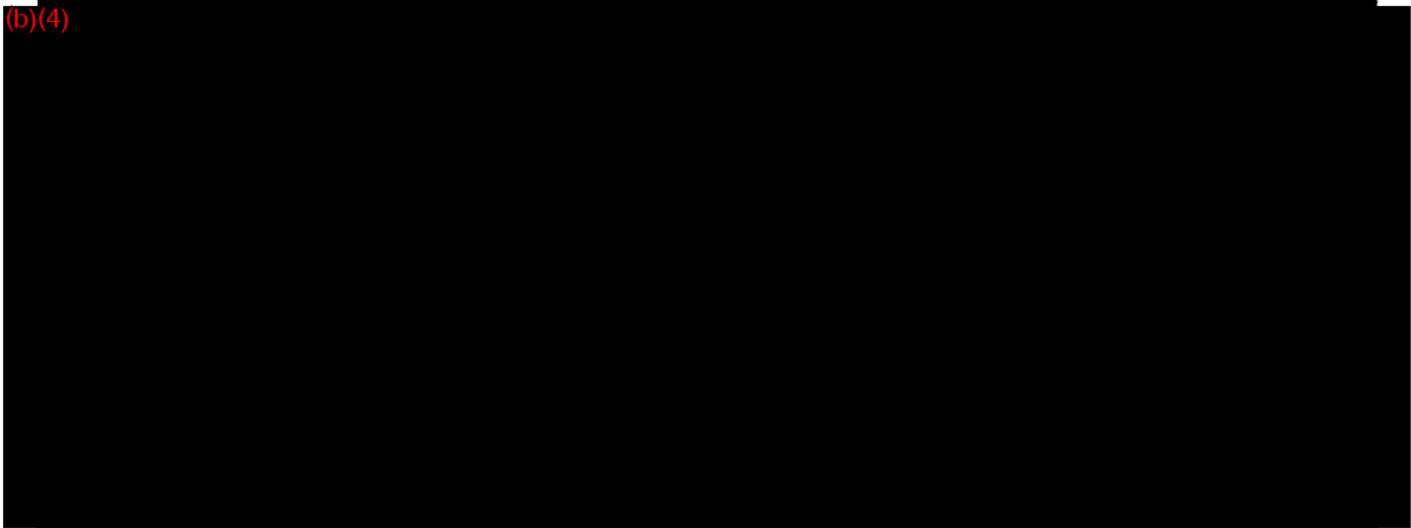
REASON FOR SUBMISSION - 510(k)

<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
<input type="checkbox"/> Other Reason (<i>specify</i>):		

145 005

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.		FDA Document Number (if known)	
SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number 1314412	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name Tyco Healthcare LLP		Establishment Registration Number 1314412	
Division Name (if applicable) Kendall		Phone Number (including area code) (315) 821-3208	
Street Address 130 South Main Street		FAX Number (including area code) ()	
City Oriskany Falls		State / Province NY	ZIP/Postal Code 13425
Contact Name Bob Klumbach		Contact Title QA Manager	Contact E-mail Address robert.klumbach@Tycohealthcare.com

(b)(4)



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

146 0066

SECTION I

UTILIZATION OF STANDARDS

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

	Standards No.	Standards Organization	Standards Title	Version	Date
1	10993-1	ISO	Biological evaluation of Medical Devices – part 1: Evaluation and testing	3 rd Ed	2003
2	11135	ISO	Validation and routine control of Ethylene Oxide Sterilization	1994	1994
3	10993-7	ISO	Biological evaluation of Medical Devices – part 7: Ethylene oxide sterilization residuals	1 st Ed	1995
4					
5					
6					
7					

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

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

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

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

147 007

510(k) Premarket Notification
COPA AMD Antimicrobial Wound Dressing

Premarket Notification: Truthful and Accurate Statement

I certify that, in my capacity as Vice President, Regulatory Affairs of Kendall, a Division of Tyco Healthcare Group, LP, I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material facts have been omitted.


James Welsh

5-11-07
Date

510(k) Premarket Notification
COPA AMD Antimicrobial Wound Dressing

Section A – General Device Summary

COPA AMD Antimicrobial Wound Dressing

Date of Submission:	May 11, 2007
Proprietary Name:	COPA AMD Antimicrobial Wound Dressing
Common Name:	Wound Dressing, Antimicrobial
Classification Name:	Dressing, Wound, Occlusive
FDA Product Code:	NAD
FDA Device Class :	Class I, Not exempt from 510k per 21CFR 878.9(b)

Establishment Registration

Manufacturing Facility Address:	Kendall a Division of Tyco Healthcare Group LP 130 South Main Street Oriskany Falls, NY 13425
FDA Establishment Registration Number:	1314412
Sterilization Site:	Sterigenics 84 Park Road Queensbury, NY 12804
FDA Facility Registration Number:	1319639

Sponsor Information

Sponsor Name and Address:	Kendall a Division of Tyco Healthcare Group LP 15 Hampshire Street Mansfield, MA 02048
FDA Establishment Registration #:	1282497

510(k) Premarket Notification
COPA AMD Antimicrobial Wound Dressing

Section A – General Device Summary (Continued)

Sponsor Information (continued)

Contact Information:

James Welsh
VP, Regulatory Affairs
Kendall
a Division of Tyco Healthcare Group LP
15 Hampshire Street
Mansfield, MA 02048
Phone: (508) 261-8532
Fax: (508) 261-8461

Purpose of Submission

The purpose of this submission is to obtain FDA clearance for a polyurethane foam wound dressing which contains PHMB (Polyhexamethylene Biguanide Hydrochloride) to inhibit microbial growth within the dressing. This notification includes the appropriate information to demonstrate substantial equivalence of the proposed device to the legally marketed predicate device. A 510(k) summary is provided in **Section B** of this notification.

Indications / Intended Use

COPA AMD dressings are indicated for use in management of post-surgical incisions, pressure sores, venous stasis ulcers, diabetic ulcers, donor sites, abrasions, lacerations, 1st and 2nd degree burns, dermatologic disorders, other wounds inflicted by trauma and, as a secondary dressing or cover dressing for packed wounds. COPA AMD dressings may be used on infected wounds as part of the overall medical treatment where a foam dressing is indicated for protection of the wound. The barrier function of this wound dressing may help reduce wound infections.

The Indications for Use Statement is provided in **Appendix 1** of this notification.

Performance Standards

No applicable performance standards pertaining to this device have been issued under section 514 of the Food, Drug and Cosmetic Act.

Predicate Devices

Curafoam Polyurethane Foam Dressings, K946269, cleared 1/12/95

Kerlix AMD Antimicrobial Gauze Dressing K990530, cleared 1/31/00

Excilon AMD Antimicrobial Sponge K011941, cleared 8/22/01

510(k) Premarket Notification
COPA AMD Antimicrobial Wound Dressing

Section A – General Device Summary (Continued)

Substantial Equivalence

The polyurethane foam dressings originally cleared as Curafoam in K946269 are now marketed under the brand name of COPA. The letters COPA are not an acronym, simply a trademark. COPA AMD dressings are substantially equivalent to the existing COPA (Curafoam) dressings, with the only difference being the addition of PHMB as an antimicrobial agent to protect the dressing from bacterial penetration and colonization. The indications for use of COPA (Curafoam) dressings are essentially identical to that sought for COPA AMD. The differences are specific to the antimicrobial component.

The use of PHMB to protect wound dressings from bacterial penetration and colonization was cleared via K990530 for our company's Kerlix AMD (cotton) wound dressings and via K011941 for our Excilon AMD (rayon-polyester) sponges. The indications for use of Kerlix AMD and Excilon AMD are essentially identical to that sought for COPA AMD. The differences are attributable to the fabric vs. foam dressing types.

Proposed product configurations

The proposed dressings will be available in a variety of shapes and sizes, ranging from 1 inch diameter round disks, to 6 inch squares. The COPA AMD product will be available in the same 3 styles as the Current COPA product:

- foam pads (regular) COPA AMD
- foam pads with a liquid impervious film backsheet on one side (COPA AMD Plus)
- foam pads with an oversized liquid impervious backsheet that includes an adhesive border (COPA AMD Island).

The dressings will be individually packed in sterile barrier pouches, and will be sold in boxes of multiple dressings. The product will be sold sterile. There are no accessories or kit components.

510(k) Premarket Notification
COPA AMD Antimicrobial Wound Dressing

Section C– Labels and Labeling

This section contains representative draft labels and Instruction For Use for the new COPA AMD product. The instruction for use labeling is drafted in accordance with 21 CFR Part 801.

The instructions for use and labeling for the predicate devices are included in this section for comparison purpose. The instructions for use are common to all styles, COPA AMD, COPA AMD Plus, and COPA AMD Island. The example package label is limited to one size of COPA AMD Island, other sizes and styles are essentially equivalent.

C1) COPA AMD Island (proposed device)

1. Unit Package (pouch) label
2. Carton label (shelf box) label
3. Case (shipment package) label
4. Instructions for use

C2) COPA Island (K946269)

1. Unit package (pouch) label
2. Carton label
3. Case label
4. Instructions for use (common to all sizes and styles)

C3) Kerlix AMD (K990530)

1. Unit package (pouch) label
2. Carton label
3. Instructions for use (common to all sizes and styles)

C4) Excilon AMD (K011941)

1. Unit package (pouch) label
2. Carton label
3. Instructions for use (common to all sizes and styles)

COPA™ AMD™ ISLAND



REF
55588BAMD

8" x 8"
(20 cm x 20 cm)

Adhesive Bordered Antimicrobial Foam Dressings
 Pansement hydrocellulaire antimicrobien avec bordure adhésive
 Antimikrobieller Schaumstoffverband mit Haftband
 Medicazione antimicrobica in schiuma con bordi adesivi
 Apósito de espuma antimicrobiana con bordes adhesivos
 Antimikrobiell skumforband med självhäftande kanter
 Antimicrobieel schuimverband met plakkende rand
 Penso de espuma antimicrobiana com bordo adesivo
 Liimareunainen antimikrobinen vaahdotmuovuisidos



STERILE EO



LOT

Use By
2000-00

000000



Keep Away
From Sunlight

RX ONLY

Single Use

1260806

0003

tyco / Healthcare

KENDALL

COPA™ AMD™ ISLAND



REF
55588BAMD

8" x 8"
(20 cm x 20 cm)

Antimikrobiel skumbandage med selvklæbende kanter
 Αντιμικροβιακό αφρώδες επίθεμα με αυτοκόλλητο περιθώριο
 Antimikrobiální pěnové krytí s adhezivním okrajem
 Ragasztós szélű antimikrobiális habszivacsótszer
 Антимикробная повязка из полиуретановой губки с клейкими краями
 Przeciwbakteryjny oprutek piankowy z samoprzylepnym obramowaniem
 Yarışkan Kenarlı Antimikrobiik Köpük Yara Örtüsü
 Antimikrobiell skumbandasje med selvhæftende kanter



0.5% Polyhexamethylene Biguanide (PHMB)

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GOSPORT PO13 0AS, U.K.



5050683007891

PZN - 1875551



(01)30694393109900



(10)000000

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KENDALL

818
156

**INSTRUCTIONS FOR USE/ PACKAGE INSERT
COPA™ AMD™, COPA™ AMD™ PLUS, COPA™ AMD™ ISLAND**

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PRODUCT INFORMATION IN U.S. 1-800-962-9888-www.TycoHealthcare.com

EC REP TYCO HEALTHCFARE U.K. LTD. Gosport PO13 OAS, U.K.

DESCRIPTION

COPA™ AMD™ Antimicrobial Foam Dressings provide an ideal moist wound healing environment for a wide variety of wounds. This highly absorbent, non-linting dressing is designed to protect and cushion moderate to heavily exuding wounds. COPA AMD Dressings are semi-occlusive allowing the exchange of gases such as oxygen and water vapor. The soft flexible nature of the COPA AMD dressing allows it to conform easily to all body contours. COPA AMD Dressings are non-adherent, and non-drying, making dressing changes easy and minimizing pain.

COPA AMD Dressings provide an antimicrobial barrier to bacteria penetration through the dressing and prevents colonization and proliferation of bacteria within the dressing for up to seven days. By limiting the microbial growth in wound exudates, the bioburden load on healing tissue is minimized.

INDICATIONS FOR USE

COPA AMD dressings are indicated for use in management of post-surgical incisions, pressure sores, venous stasis ulcers, diabetic ulcers, donor sites, abrasions, lacerations, 1st and 2nd degree burns, dermatologic disorders, other wounds inflicted by trauma and, as a secondary dressing or cover dressing for packed wounds. It is an ideal dressing in the local management of exudate that may occur at surgically induced body drainage sites such as tracheostomy, G-tube, J-tube, Penrose drain, chest tube, nephrotomy tube or sump drain. COPA AMD dressings may be used on infected wounds as part of the overall medical treatment where a foam dressing is indicated for protection of the wound. The barrier function of this dressing may help reduce wound infections.

**INSTRUCTIONS FOR USE/ PACKAGE INSERT
COPA™ AMD™, COPA™ AMD™ PLUS, COPA™ AMD™ ISLAND**

PRECAUTIONS

- For external use only
- Do not use as a primary treatment for infected wounds
- Do not use as a primary treatment for full 3rd degree burns
- Do not use on patients with known sensitivity to PHMB
- Do not use if primary package is damaged.
- Do not resterilize
- Single use only

PREPARING THE WOUND SITE

Cleanse the wound area if necessary using a non-toxic cleansing solution such as CONSTANT CLENS™ or saline. Rinse and dry the wound and surrounding areas thoroughly before dressing application.

APPLYING THE DRESSING

Select the dressing which will provide a minimum of a 2 inch (5 cm) foam margin around the edges of the wound. If necessary, cut the dressing to size to ensure a smooth, continuous fit with the skin surface. (COPA™ AMD™ Dressings should be applied with the foam side touching the dressing site or with the topsheet facing up).

Place COPA AMD Dressing directly onto the wound surface and hold in place by covering with POLYSKIN™ II Dressing, Kerlix™ or CURITY™ Gauze Bandage Rolls, TENSOR™ Elastic Bandage, CONFORM™ Stretch Bandage, adhesive tape or other appropriate secondary dressing. If using COPA AMD Island Dressings, use of the above mentioned products will not be needed to hold the dressing in place.

FREQUENCY OF CHANGE

The high absorbency and sustained antimicrobial efficacy of COPA AMD Dressings allows the user to comply with established treatment protocols for

**INSTRUCTIONS FOR USE/ PACKAGE INSERT
COPA™ AMD™, COPA™ AMD™ PLUS, COPA™ AMD™ ISLAND**

foam dressings, up to one week between dressing changes.. In typical use, the frequency of changes will depend upon the nature and condition of the wound and the amount of exudate.

DRESSING CHANGE AND REMOVAL

The COPA™ AMD™ Dressing should be changed when signs of saturation are visible along the edge of the dressing or whenever good nursing practice dictates. To change the dressing, remove the securing bandages or tape and carefully lift COPA AMD Dressing off the wound. COPA AMD Dressings are non-adherent, non- adhesive, and non-gelling.

DRESSING EXPANSION

COPA AMD Dressings absorb exudate and will expand and 'grow' in size due to the cellular structure of the dressing.

ORDERING INFORMATION

<i>REF</i>	<i>Description</i>	<i>Quantity per Carton</i>	<i>Quantity per Carton</i>
<u>COPA™ AMD™ Antimicrobial Foam Dressing</u>			
55522AMD	2 in X 2 in COPA AMD Foam Dressing	10	50
55544AMD	4 in X 4 in COPA AMD Foam Dressing	10	50
55566AMD	6 in X 6 in COPA AMD Foam Dressing	10	50
55535AMD	3 ½ in X 3 in COPA AMD Fenestrated Foam Dressing	10	50
55511AMD	1" Diameter COPA AMD Fenestrated Foam Dressing	10	50
<u>COPA™ AMD™ PLUS Antimicrobial Foam Dressing</u>			
55544PAMD	4 in x 4 in COPA AMD PLUS Foam Dressing	10	50
<u>COPA™ AMD™ Island Antimicrobial Foam Dressing</u>			
55566AMD	4 in X 4 in Pad Size	10	50
55588AMD	6 in X 6 in Pad Size	10	50

↓ DIRECTION THROUGH MACHINE ↓



tyco / Healthcare



REF 55588B

KENDALL

COPA™ ISLAND

Adhesive Bordered Foam Dressing

8" x 8" (20 cm x 20 cm)

Pansement en mousse à bords adhésifs
 Schaumstoffwundauflagen mit Kleberand
 Medicazioni di Spugna con Bordi Adesivi
 Apósitos de goma espuma con bordes adhesivos
 Skumkompresser med självhäftande kanter
 Schuimverbanden met Plakrand
 Compressas de Espuma com Rebordo Adesivo



STERILE EO

Do not use if unit package is opened or damaged.

CE 0123

Single Use See Accompanying Documents



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160 022

tyco / healthcare
KENDALL
COPA ISLAND
Adhesive Bordered Foam Dressings

555888

555888

tyco / healthcare
KENDALL
COPA ISLAND
Adhesive Bordered Foam Dressings

8" x 8" (20 cm x 20 cm)

Puskesmas en roussa à bord adhésive
 Schwammstoffrandverbände mit Kleberand
 Mediasioni di Spugna con Bordo Adesivo
 Adhésive de goma e espuma con bordos adhesivos
 Schaumstoffverbände mit Kleberand
 Compressas de Espuma com Bordo Adesivo

STERILE EO
 CE 0123
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728-3343279
 0517 7040491510307711

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KENDALL
COPA ISLAND
Adhesive Bordered Foam Dressings

555888

555888

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KENDALL
COPA ISLAND
Adhesive Bordered Foam Dressings

8" x 8" (20 cm x 20 cm)

Puskesmas en roussa à bord adhésive
 Schwammstoffrandverbände mit Kleberand
 Mediasioni di Spugna con Bordo Adesivo
 Adhésive de goma e espuma con bordos adhesivos
 Schaumstoffverbände mit Kleberand
 Compressas de Espuma com Bordo Adesivo

STERILE EO
 CE 0123
 10

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KENDALL
COPA ISLAND
Adhesive Bordered Foam Dressings

555888

555888

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KENDALL
COPA ISLAND
Adhesive Bordered Foam Dressings

8" x 8" (20 cm x 20 cm)

Puskesmas en roussa à bord adhésive
 Schwammstoffrandverbände mit Kleberand
 Mediasioni di Spugna con Bordo Adesivo
 Adhésive de goma e espuma con bordos adhesivos
 Schaumstoffverbände mit Kleberand
 Compressas de Espuma com Bordo Adesivo

STERILE EO
 CE 0123
 10

COPA™ ISLAND REF55588B

Adhesive Bordered Foam Dressing

Pansement en mousse à bords adhésifs

Schaumstoffwundauflagen mit Kleberand

Medicazioni di Spugna con Bordi Adesivi

8" x 8"
(20 cm x 20 cm)



50

CE 0123

Use By
2000-00

STERILE EO

LOT
123456

Keep Away From Heat

Single Use

Keep Dry

tyco / Healthcare

KENDALL

0800206
0001



5050683005279



PZN-6343379



(01)30694393047738



(10)123456

COPA™ ISLAND REF55588B

Apósitos de goma espuma

con bordes adhesivos

Skumkompresser med självhäftande kanter

Schuimverbanden met Plakrand

Compressas de Espuma com Rebordo Adesivo

8" x 8"
(20 cm x 20 cm)



50



5050683005279



PZN-6343379



(01)30694393047738



(10)123456

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www.tycohealthcare.com

TYCO HEALTHCARE U.K. LTD.

GOSPORT, PO13 0AS, U.K.

tyco / Healthcare

KENDALL

English

DESCRIPTION: COPA Hydrophilic Foam Dressings provide an ideal moist environment for a wide variety of wounds. This highly absorbent, non-limiting dressing is designed to protect and cushion moderate to heavily exuding wounds. COPA Dressings are semi-occlusive allowing the exchange of gases such as oxygen and water vapor. The soft, flexible nature of the COPA Dressing allows it to conform easily to all body contours. COPA Dressings are non-adherent, making dressing changes easy and comfortable.

INDICATIONS FOR USE: Post-surgical incisions, pressure sores, venous stasis ulcers, diabetic ulcers, donor sites, abrasions, lacerations, superficial burns, other wounds inflicted by trauma and, as a secondary dressing or cover dressing for packed wounds. It is an ideal dressing in the local management of exudate that may occur at surgically induced body drainage sites such as a tracheostomy, G-tube, J-tube, Penrose drain, chest tube, nephrotomy tube or sump drain.

PRECAUTIONS: COPA Dressings are not intended for full thickness burns.

PREPARING THE WOUND SITE: Cleanse the wound area if necessary using a non-toxic cleaning solution such as **CONSTANT-CLENS™** or saline. Rinse and dry the wound and surrounding areas thoroughly before dressing application.

APPLYING THE DRESSING: Select the dressing which will provide a minimum of a 2 inch (5 cm) foam margin around the edges of the wound. If necessary, cut the dressing to size to ensure a smooth, continuous fit with the skin surface. (COPA Dressings should be applied with the white side touching the dressing site or with topsheet up.)

Place COPA Dressing directly onto the wound surface and hold in place by covering with **POLYSKIN™ II Dressings**, **KERLIX™** or **CURITY™ Gauze Bandage Rolls**, **TENSOR™ Elastic Bandage**, **CONFORM™ Stretch Bandage**, adhesive tape or other appropriate secondary dressing. If using **COPA ISLAND Dressings**, use of the above-mentioned products will not be needed to hold the dressing in place.

FREQUENCY OF CHANGE: The high absorbency of COPA Dressings minimizes the need for dressing changes. In actual use, the frequency of changes will depend upon the nature and condition of the wound and the amount of exudate. For clean, superficial wounds, without any signs of saturation or infection, COPA Dressings may be left in place for up to one week.

DRESSING CHANGE AND REMOVAL: The COPA Dressing should be changed when signs of saturation are visible along the edge of the dressing or whenever good nursing practice dictates. To change the dressing, remove the securing bandages or tape and carefully lift COPA Dressing off the wound. COPA Dressings are non-adherent, non-adhesive and non-gelling. Dressing changes are fast, comfortable and will not disrupt healing granulation tissue.

DRESSING EXPANSION: COPA Dressings absorb exudate and will expand and "mush" in size due to the cellular structure of the dressing.



KENDALL
COPA™
Hydrophilic Foam Dressings

- Pansements en mousse hydrophile
- Hydrophile Schaumstoffverbände
- Bende di schiuma idrofila
- Apósitos de espuma hidrófila
- Hydrofila skumförband
- Hydrofiel schuimverband
- Pensos de espuma hidrofílica
- Vettä imevät vaahтомуovisidokset
- Hydrofile skumbandager
- Υδροφιλοι αφρώδεις επίδεσμοι
- Hydrofilní pěnová krytí
- Nedvességtartó habszivacskötszerek
- Повязки с гидрофильной пеной
- Hydrofilowe opatrunki piankowe
- Hidrofilij Köpük Sarğılar

COPA™ PLUS, COPA™ ISLAND

STERILE EO CE 0123

Keep Away From Heat

Single Use

MADE WITH POLYURETHANE

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0360405

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KENDALL

KERLIX™ AMD™

Antimicrobial Super Sponges

Eponges maxi antimicrobiennes
Antimikrobielle Super-Tupfer
Spugne antibatteriche grandi
Super esponjas antimicrobianas
Antimikrobiella extra
uppsugande torkar
Antimikrobiële superwondgaasjes
Super-esponjas antimicrobianas

LOT CODE &
EXPIRATION



Single Use

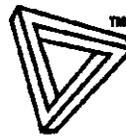
HYPOALLERGENIC



HCPCS: A6223

STERILE EO

Do not use if package is opened or damaged.



REF

6662

Medium – Diagonals Measure 6" x 6.75" (15 cm x 17 cm) Stretched

Étiré • Gedeht • Disteso • Estiradas
Sträckt • Uitgetrokken • Esticado



Moyen – Mesure des diagonales
Mittelgroß – Diagonalmäß
Media – misura delle diagonali
Medianas – las diagonales miden
Medium – Diagonalmått
Medium – Diagonale maat
Médio – Medida na diagonal



CAUTION: Not intended as a treatment for clinical infection. If signs of clinical infection are present, consult a physician. KERLIX AMD Dressings can be used in conjunction with the prescribed therapy.

INDICATIONS: Primary dressing for exuding wounds, first and second degree burns, surgical wounds, and wound packing. Securement of primary dressing.

CONTAINS: Polyhexamethylene Biguaride (0.2%).

2



FOR POSITION ONLY

(01) 10694393047338

U.S. Pat. No. 6,369,289 and pending counterparts.

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1969322

164 026

STERILE EO

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KENDALL

KERLIX™ AMD™

Antimicrobial Super Sponges

Medium - Diagonals Measure

6" x 6.75" (15 cm x 17 cm) Stretched

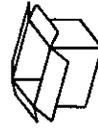
Stretched • Étiré • Gedeht • Diktoso • Estiradas • Sträckt • Ullgetrokken • Esticado • Venyitettynä
Strakt • Σε έκταση • Roztažené • Kinyújtó • Распрямляющиеся • Rozciągające • Gerilmiş

Medium - Diagonals Measure
Moyen - Mesure des diagonales
Mittelgroß - Diagonalmäß
Media - misura delle diagonali
Medianas - las diagonales miden
Medium - Diagonalmått

Medium - Diagonale maat
Médio - Média na diagonal
Keskikoko - Kävståjän mitta
Mittidet - Diagonalmål
Moodid - Me diagonaalide mõõtmiseks
Orta - Çaprazlamasın Ölçü



Antimicrobial Super Sponges
Eponges maxi antimicrobiennes
Antimikrobielle Super-Tupfer
Spugne antibatteriche grandi
Super esponjas antimicrobianas
Antimikrobiella extra uppsugande torkar
Antimicrobiële superwondgaasjes
Super-esponjas antimicrobianas
Antimikrobiset supersienet
Antimikrobielle supersvampe
Αντιμικροβιακά σούπερ σπόγγοι
Antimikrobiální speciální houbičky
Antibakteriális szuper tampon
Противомикробные супертампоны
Super gąbki przeciwbakteryjne
Antimikrobiyal Süper Süngerler



480

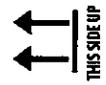
REF 6662

HCPCS: A6223



PAPER 1

STERILE EO



REF 6662

tyco / Healthcare

KENDALL

KERLIX™ AMD™

Antimicrobial Super Sponges

Medium – Diagonals Measure
6" x 6.75" (15 cm x 17 cm) Stretched

Stretched • Etiré • Gedehnt • Disteso • Estradado • Sträckt • Utigetrocken • Esticado • Venytettyinä
Straakt • Зэ ёкчам • Roztažené • Kinyújtva • Paccrивaющeся • Rozciągające • Geilmitş

Medium – Diagonals Measure
Moyen – Mesure des diagonales
Mittelgroß – Diagonalmass
Media – măsura diagonalei

Medianas – las diagonales miden
Medium – Diagonalmått
Medium – Diagonale maat
Médio – Medida na diagonal

Keskikoko – lävistäjän mitta
Mitteli – Diagonalmått
Keskia – Mē dōrcōuō ōuyayūlav
Sittēdīnē veltē – Čtvercový tvar

Közepes – Átlós méret
Crepșero pãimerepa – Diagonali
Sredine – Mierzone po ukosie
Orta – Çaprazlamasin ölçü

HCPCS: A6223

480

PHASE 2

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STERILE EO

tyco / Healthcare

KENDALL

KERLIX™ AMD™

Antimicrobial Super Sponges

Medium – Diagonals Measure

6" x 6.75" (15 cm x 17 cm) Stretched

Stretched • Etirado • Disteso • Estradado • Ullgjerokken • Estirado • Venyítettyná
Strakti • Szécsomog • Roztaženo • Ruvyžhiva • Paktaruaaowico • Roctqatqete • Gerfimy

Medium – Diagonals Measure
Mesura des diagonales
Mittelmäß – Diagonalmass
Medida – misura delle diagonali
Mediannas – las diagonales miden
Medium – Diagonalmått

Střední veliké – Zvercový tvar
Közepes – Átlós méret
Среднего размера – Квадратный
Средние – Метроне по диагонали
Orta – Çaprazlamam ölçü



Antimicrobial Super Sponges
Eponges maxi antimicrobiennes
Antimikrobielle Super-Tupfer
Spugne antibakterielle grandi
Super esponjas antimicrobianas
Antimikrobiella extra uppsugande torftar
Antimicrobiële superwondgasjes
Super-esponjas antimicrobianas
Antimikrobiel superienet
Antimikrobielle superwampe
Авгукробољакот ооѓрег отовывој
Antimikrobiální speciální houbičky
Antibakteriális szuper tampon
Противомикробные супертампоны
Super gąbki przeciwbakteryjne
Antimicrobial Super Sponger



480 ▶

REF 6662

HCPCS: A6223



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Corrugated Recycles

PAGE 3

168

STERILE EO

tyco / Healthcare

KENDALL

KERLIX™ AMD™

Antimicrobial Super Sponges

Medium – Diagonals Measure
6" x 6.75" (15 cm x 17 cm) Stretched

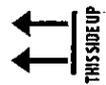
Stretch - Etiré • Gedeht • Disteso • Estradas • Strácht • Utigetrokken • Esticado • Venyttynä
Strakt • Σε Εκταση • Roztažené • Kinyúlva • Paccrивaющecs • Rozciągnięte • Geilimş

Medium – Diagonals Measure
Moyen – Mesure des diagonales
Mittelgroß – Diagonalmß
Media – misura delle diagonali

Mediana – As diagonales miden
Medium – Diagonalmitt
Medium – Diagonale maat
Médio – Médida na diagonal

Keskikoko – Järvistään mita
Middel – Diagonalmål
Kisacsa – Né átlósraaj önyomulaj
Středně velké – čtvercový tvar

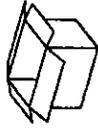
Közepes – Átlós méret
Среднего размера – Квадратна
Srednie – Mierzone po ulosie
Orta – Çaprazlamasin Ölçü



REF

6662

HCPCS: A6223



480 ▶

PAKED
4



tyco / Healthcare

KENDALL

KERLIX™ AMD™

Antimicrobial Products

Produits antimicrobiens
Antimikrobielle Mittel
Prodotti antimicrobici
Productos antimicrobianos
Antimikrobiella produkter
Antimicrobiële producten
Produtos antimicrobianos
Antimikrobiset tuotteet
Antimikrobielle produkter
Προϊόντα με αντιμικροβιακή δράση
Antimikrobiální výrobky
Antimikrobás termékek
Антимикробные продукты
Przeciwbakteryjne produkty
Anti Mikrobik Ürünler

STERILE EO HYPOALLERGENIC



HCPCS: A6266



English

CAUTION: Not intended as a treatment for clinical infection. If signs of clinical infection are present, consult a physician. KERLIX AMD Dressings can be used in conjunction with the prescribed therapy.

INDICATIONS: Primary dressing for exuding wounds, first and second degree burns, surgical wounds, and wound packing. Securement of primary dressing.

CONTAINS: Polyhexamethylene Biguanide (0.2%).

Français

ATTENTION : Non indiqué pour le traitement des infections cliniques. En cas de signes d'infection clinique, consulter un médecin. Les pansements KERLIX AMD sont utilisables en association avec le traitement prescrit.

INDICATIONS : Pansement primaire pour plaies suintantes, brûlures du premier et du deuxième degré, plaies chirurgicales et remplissage de plaies. Consolidation de pansements primaires.

COMPOSITIONS : Polyhexaméthylène biguanide (0,2 %).

Deutsch

VORSICHT: Nicht als Behandlung für klinische Infektionen vorgesehen. Bei Anzeichen einer klinischen Infektion einen Arzt hinzuziehen. KERLIX AMD-Verbände können in Verbindung mit der verordneten Therapie verwendet werden.

INDIKATIONEN: Primärverband für nässende Wunden, Verbrennungen ersten und zweiten Grades, Operationswunden und Wundfüller. Fixierung des Primärverbands.

INHALT: Polyhexamethylenbiguanid (0,2 %).

Italiano

ATTENZIONE: non indicato come trattamento di infezioni cliniche. Se sono presenti segni di infezioni cliniche, consultare il medico. È possibile usare le bende KERLIX AMD unitamente alla terapia prescritta.

INDICAZIONI: fasciature primarie per ferite con essudato, ustioni di primo e secondo grado, ferite chirurgiche e tamponamento di ferite. Per fissare le fasciature primarie.

CONTIENE: poliesametilene biguanide (0,2%).

Español

PRECAUCIÓN: No está previsto como tratamiento para infección clínica. Si hay signos de infección clínica, consultar al médico. KERLIX AMD Los apósitos se pueden usar junto con la terapia prescrita.

INDICACIONES: Apósito primario para lesiones supurantes, quemaduras de primer y segundo grado, lesiones quirúrgicas y taponamiento de heridas. Medio para sujetar el apósito primario.

CONTIENE: Biguanido polihexametileno (0,2 %).

Svenska

OBS! Ej avsedd som behandling av kliniskt manifest infektion. Vid tecken på kliniskt manifest infektion skall läkare kontaktas. KERLIX AMD förband kan användas i samband med pågående ordinerad behandling.

INDIKATIONER: Primärförband för vätskande sår, brännskador av första och andra graden, kirurgiska sår och packning av sår. Fastsättning av primärförband.

INNEÅLLER: Polyhexametylen-biguanid (0,2 %).

U.S. Pat. No. 6,369,289 and pending counterparts.

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PRODUCT INFORMATION IN U.S. 1-800-962-9888 • www.tycohealthcare.com • [EC REP] TYCO HEALTHCARE U.K. LTD. • GOSPORT, PO13 0AS, U.K.

978548

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169

tyco / Healthcare

KENDALL

EXCILON™ AMD™

Antimicrobial Drain Sponges

6 Ply - 4 in x 4 in (10 cm x 10 cm)

CONTENTS: 2 Sponges Patent Pending

INDICATIONS: For use as primary dressings for IV sites, tracheostomy tube sites, chest tube sites, catheter sites and drain sites. The antimicrobial activity of the PHMB in EXCILON AMD helps to resist bacterial colonization within the dressing and inhibit bacterial penetration through the dressing. The barrier function of the dressing may help reduce infections in partial and full thickness wounds.

CAUTION: Not intended as a treatment for clinical infection. If signs of clinical infection are present, consult a physician. EXCILON AMD Dressings can be used in conjunction with the prescribed therapy.

CONTAINS: Polyhexamethylene Biguanide (0.2%)

STERILE  Sterility guaranteed unless package is damaged or open.

KENDALL WOUND CARE PRODUCTS 

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1958275

REF

7088



Single Use



0123



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16



PZN -3928228



(01)00694393089409

REF 7088

tyco / healthcare

KENDALL

EXCILON™ AMD

Antimicrobial Drain Sponges

4 in x 4 in (10 cm x 10 cm)

Antimicrobial Drain Sponges - 6 Ply
 Éponges de drainage antimicrobiennes - 6 plis
 Antibakterielle Drainageschwämme - 6 lagig
 Spugne per drenaggio antimicrobica - 6 pezzi
 Esponjas antimicrobianas de drenaje - 6 capas
 Antimikrobiella uppsugningsvaror - 6 lagars
 Antimikrobiel intravenus sponngas - 6 lagars
 Esponjas de drenio antimicrobianas - 6 capas



54050683003664



PZN -3928228



(01)2069-4390089403

NOTES

- See the manual which contains the description of the product.
- Lire le manuel d'instructions, lequel se trouve dans le dossier de livraison de l'emballage.
- Lesen Sie die Bedienungsanleitung, welche im Lieferumfang des Produkts enthalten ist.
- Legga manuala, som är förpackningen till denna produkt.
- Consulte o manual de instruções, que se encontra no material de embalagem.

REF 7088

tyco / healthcare

KENDALL

EXCILON™ AMD

Antimicrobial Drain Sponges

4 in x 4 in (10 cm x 10 cm)

Antimicrobial Drain Sponges - 6 kerrosiset
 Antimikrobielie drainausseimet - 6 kerroksiset
 Éponges de drainage antimicrob - 6 lag
 Antibakterielle Drainageschwämme - 6 lagig
 Spugne per drenaggio antimicrobica - 6 pezzi
 Esponjas antimicrobianas de drenaje - 6 capas
 Antimikrobiella uppsugningsvaror - 6 lagars
 Antimikrobiel intravenus sponngas - 6 lagars



54050683003664



PZN -3928228



(01)2069-4390089403

NOTES

- See the manual which contains the description of the product.
- Lire le manuel d'instructions, lequel se trouve dans le dossier de livraison de l'emballage.
- Lesen Sie die Bedienungsanleitung, welche im Lieferumfang des Produkts enthalten ist.
- Legga manuala, som är förpackningen till denna produkt.
- Consulte o manual de instruções, que se encontra no material de embalagem.

REF 7088

tyco / healthcare

KENDALL

EXCILON™ AM

Antimicrobial Drain

4 in x 4 in (10 cm x 10 cm)

Antimicrobial Drain Sponges - 6
 Éponges de drainage antimicrob
 Antibakterielle Drainageschwämme
 Spugne per drenaggio antimicro
 Esponjas antimicrobianas de dre
 Antimikrobiella uppsugningsvar
 Antimikrobiel intravenus spon
 Esponjas de drenio antimicrobian

NOTES

- See the manual which contains the description of the product.
- Lire le manuel d'instructions, lequel se trouve dans le dossier de livraison de l'emballage.
- Lesen Sie die Bedienungsanleitung, welche im Lieferumfang des Produkts enthalten ist.
- Legga manuala, som är förpackningen till denna produkt.
- Consulte o manual de instruções, que se encontra no material de embalagem.

CONTENTS

2 X 25 = 50

tyco / Healthcare

KENDALL

EXCILON™ AMD™

**Antimicrobial I.V. Sponges
Antimicrobial Drain Sponges**

STERILE



Single Use



0123

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978547

English

**Antimicrobial I.V. Sponges
Antimicrobial Drain Sponges**

INDICATIONS: For use as primary dressings for surgical incisions, lacerations, abrasions, burns, donor sites, catheter sites, I.V. sites and central lines. The antimicrobial activity of the PHMB in EXCILON AMD helps to resist bacterial colonization within the dressing and inhibit bacterial penetration through the dressing. The barrier function of the dressing may help reduce infections in partial and full thickness wounds.

CAUTION: Not intended as a treatment for clinical infection. If signs of clinical infection are present, consult a physician. EXCILON AMD Dressings can be used in conjunction with the prescribed therapy.

CONTAINS: Polyhexamethylene Biguanide (0.2%)

510(k) Premarket Notification
COPA AMD Antimicrobial Wound Dressing

Section D – Device Description

Background

Wound dressings come in a variety of configurations but all achieve the same basic purpose, to cover and protect the wound from contamination. Key factors in selecting a wound dressing are the size and type of wound, and the amount of exudate (drainage) produced. Highly exuding wounds require large amounts of absorptive material and frequent dressing changes. Minimally exuding wounds such as a sutured incision site require less absorptive capacity, but still need cushioning and protection from contamination. Dry wounds that require periodic debridement benefit from a moist wound environment, both to support the healing process, and to minimize the pain of debridement and dressing changes.

In all cases, providing a wound dressing that is resistant to bacterial penetration and colonization improves the ability of the dressing to perform the primary intent; to protect the wound from contamination. This includes contamination from outside sources, as well as the uncontrolled growth within the wound dressing of organisms that originated from the wound exudates. By minimizing these sources of external contamination, the challenge to the body's own defense mechanisms (in fighting wound infection) is likewise minimized.

Kendall markets a wide range of wound dressings. We have previously introduced PHMB treated dressings for our cotton dressings (Kerlix AMD – K990530), and our nonwoven rayon-polyester cover sponges (Excilon AMD – K011941). This submission extends the AMD technology to our COPA polyurethane foam dressings (K946269).

Polyurethane Foam Dressings

Hydrophilic foam dressings are soft and conform easily to a wound. Because they are highly absorbent, they may be used on a highly exuding wound where traditional cotton dressings while highly absorbent are not suitable for direct application to the wound. For this type of wound, the amount of exudate mandates frequent dressing changes regardless of the type of dressing used.

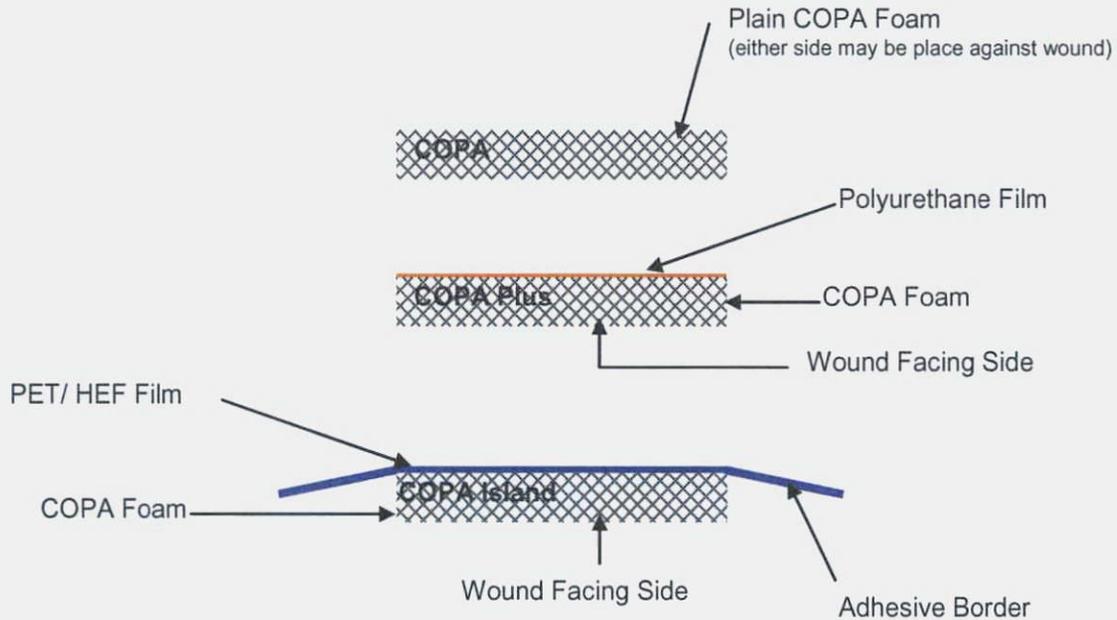
The key point that differentiates a foam dressing is that on a moderately exuding wound, they do not dry out the wound like a traditional dressing. The open cell foam structure absorbs excess fluid while maintaining a moist environment at the wound surface.

Foam dressings are ideal for chronic wounds such as pressure sores and venous ulcers, where dressings are changed on a scheduled basis unless the dressing has become saturated. The high absorbency of a foam dressing reduces the need for unscheduled changes, improving quality of life for the chronic wound patient. It is a common practice to redress chronic wounds on a weekly basis unless fluid breakthrough has occurred in the interim.

510(k) Premarket Notification
COPA AMD Antimicrobial Wound Dressing

COPA Polyurethane Foam Dressings

Below are diagrams of the COPA product offering, illustrating the three basic dressing styles.



COPA AMD Polyurethane Foam Dressings

The addition of the PHMB antimicrobial agent to the foam dressing does not impact the basic properties of the foam dressing; the only function is to inhibit bacterial growth within the dressing. As such the appearance is identical to the existing COPA product line.

Open cell foam dressings are by nature light, and have a very high surface area to weight ratio. The fluid absorption with a COPA foam dressing (15 ml liquid /gram dressing) is substantially higher than for a cotton dressing (6 ml liquid / gram of dressing). The PHMB concentration is expressed based on the dry weight of the dressing. COPA AMD contains 0.5% PHMB by weight, whereas the predicate device Kerlix AMD has 0.2% PHMB by weight. In both cases this translates to 0.33mg PHMB / ml of liquid absorption capacity.

510(k) Premarket Notification
COPA AMD Antimicrobial Wound Dressing

Materials and Manufacturing

The polyurethane foam is formed by combining a urethane pre-polymer with water. The reaction cross links the polyurethane, and releases carbon dioxide gas bubbles which form the foam as the polymer cross links. The process uses a substantial excess of water to assure complete cross linking, and to provide consistent foam cell size. The formulation also includes small quantities of surfactants to help maintain a consistent bubble diameter and resultant foam pore size.

After the foam is formed, it travels through a heat tunnel to evaporate excess moisture. The dried foam is then die cut into a finished dressing. For COPA AMD plus, the foam is applied directly to the polyurethane back sheet, no adhesives are utilized. The mixing, heating, and die cutting occur in an on-line continuous process.

For Island dressings, the die cut COPA AMD dressing is applied to an oversized adhesive back sheet.

Finished dressings are packaged in a peel pouch, boxed, and ETO sterilized

The table below lists the components of utilized to make both COPA and COPA AMD foam. After cross linking, the foam forms a 3 dimensional polymer. For COPA AMD, the PHMB is added during the foaming process so that it is thoroughly dispersed throughout the foam.

Table 1 Materials of Construction

Component Name	% by weight	Manufacturer
(b)(4) urethane pre-polymer	40.5	(b)(4)
USP purified water	58.6	produced internally
(b)(4) surfactant)	0.3	(b)(4)
(b)(4) surfactant)	0.6	(b)(4)
Polyhexamethylene Biguanide Hydrochloride (PHMB) (a.k.a. Cosmocil CQ)	5 mg per gm of foam dry weight	(b)(4)
Polyurethane backsheet (COPA AMD Plus) – (b)(4)		(b)(4)
Backsheet (COPA AMD Island) – Urethane Polyester Laminate, (b)(4)		(b)(4)
Adhesive border (COPA AMD Island) (b)(4)	17 mg per gm of dry foam weight	(b)(4)

037
175

510(k) Premarket Notification
COPA AMD Antimicrobial Wound Dressing

Performance Standards

There are currently no performance standards established and required for this device. Refer to section F for a discussion of design control activities that were employed in the development and evaluation of the COPA AMD design.

Biological Specifications

This wound dressing is categorized as a surface device, having contact with breached or compromised skin, and prolonged contact duration (24 hours - 30 days) according to ISO 10993-1 and FDA Blue Book Memorandum G95-1.

The following studies were conducted:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic Toxicity
- Sub chronic Toxicity

The product passed all of these tests, the test report is provided in appendix 2.

510(k) Premarket Notification
COPA AMD Antimicrobial Wound Dressing

Section E - Descriptive Comparison to Legally Marketed Devices

The following tables provide side-by-side comparisons of the proposed and predicate devices:

	COPA AMD (Proposed)	COPA (Curafoam) (predicate, K946269)	Kerlix AMD (predicate, K990530)	Excilon AMD (predicate, K011941)
Indications for use	COPA AMD dressings are indicated for use in management of post-surgical incisions, pressure sores, venous stasis ulcers, diabetic ulcers, donor sites, abrasions, lacerations, 1 st and 2 nd degree burns, dermatologic disorders, other wounds inflicted by trauma and, as a secondary dressing or cover dressing for packed wounds. COPA AMD dressings may be used on infected wounds as part of the overall medical treatment where a foam dressing is indicated for protection of the wound. The barrier function of this wound dressing may help reduce wound infections.	Post surgical incisions, pressure sores, venous stasis ulcers, diabetic ulcers, donor sites, abrasions, lacerations, superficial burns, other wounds inflicted by trauma, and as a secondary dressing or cover dressing for packed wounds.	Primary dressing for exuding wounds, first and second degree burns, surgical wounds, and wound packing. Securement of primary dressing.	For use as a primary dressing for IV sites, chest tube sites, catheter sites, and drain sites. The antimicrobial activity of the PHMB in Excilon AMD helps to resist bacterial colonization of the dressing and inhibit penetration through the dressing. The barrier function of the dressing may help to reduce infections in partial and full thickness wounds.
Materials of construction				
Primary structure	Polyurethane foam	Polyurethane Foam	Cotton	Non-woven polyester/rayon blend
Antimicrobial component	0.5 % PHMB	None	0.2 % PHMB	0.2 % PHMB
Packaging	Single use peel pouch	Single use peel pouch	Single use peel pouch	Single use peel pouch
Sterility	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Steam
FDA product classification	NAD (Class 1)	KMF (Class 1)	NAD (Class 1)	EFQ (unclassified)

510(k) Premarket Notification
COPA AMD Antimicrobial Wound Dressing

Section E - Descriptive Comparison to Legally Marketed Devices (continued)

Conclusion of Comparison

As shown in above tables, the similarities between the proposed device and the predicate device include:

- The proposed intended use is consistent with what has been previously cleared for the predicate devices
- Identical dressing material
- Identical antimicrobial agent.
- Established sterilization methods

The contrast between the proposed device and the predicate devices is the new application of PHMB antimicrobial agent to foam dressings. As explained in section D, the higher dry weight concentration of PHMB in the foam dressing is required to achieve the same ratio of PHMB to absorbed fluid (0.33mg / ml of fluid capacity).

The addition of PHMB to the COPA polyurethane foam dressing does not present significant new safety or efficacy issues based on the design control activities. The COPA AMD dressings are thus considered substantially equivalent to the legally marketed devices.

The product classifications assigned to the predicate devices have varied significantly. Based on the descriptions provided in the CFR, and previous history, it is believed that NAD is the most appropriate classification. It should be noted that PHMB is not a drug, but is recognized by the US EPA as (among other uses) a disinfectant for hard surfaces in direct food contact. (EPA case # 3122).

NAD – Occlusive wound dressing

An occlusive wound dressing is a nonresorbable, sterile or non-sterile device intended to cover a wound, to provide or support a moist wound environment, and to allow the exchange of gases such as oxygen and water vapor through the device. It consists of a piece of synthetic polymeric material, such as polyurethane, with or without an adhesive backing. This classification does not include an occlusive wound dressing that contains added drugs such as antimicrobial agents, added biologics such as growth factors, or is composed of materials derived from animal sources. (as stated above, PHMB is not a drug)

KMF – Liquid Bandage

A liquid bandage is a sterile device that is a liquid, semiliquid, or powder and liquid combination used to cover an opening in the skin or as a dressing for burns. The device is also used as a topical skin protectant.

EFQ – Gauze, Sponge, Internal (Unclassified, reason pre-amendment)

510(k) Premarket Notification
COPA AMD Antimicrobial Wound Dressing

Section F – Summary of Design Control Activities

Risk analysis

Risk analysis based on FMEA and ISO 14971 was conducted on the proposed COPA AMD wound dressing. Since the underlying polyurethane foam design is identical to the existing COPA dressings, there was substantial history and data to draw upon in addressing the required physical properties of the dressing. The Design FMEA is provided in appendix 3.

As a result of the risk analysis, specific verification and validation tests were identified and acceptance criteria established to ensure the continued safety and efficacy of the device.

Verification and Validation

One overlying risk is that certain key parameters are directly tied to PHMB concentration, and like any process there will be some level of variation in the level of PHMB in an individual dressing. To address this, special runs of COPA AMD were produced to provide a realistic estimate of worst case process variation in PHMB concentration. As noted in the reports provided in the appendices, these runs were designated as run 11 (low) run 12 (nominal) and run 13 (high)

For evaluation of the antimicrobial performance, run 11 was utilized, which has a PHMB level of (b)(4) vs. a specification nominal of (b)(4). The results are summarized below.

For evaluation of product biocompatibility, run 13 was utilized, which has a PHMB level of (b)(4). All tests requirements were met, the test report is provided in appendix 2.

Beyond biocompatibility testing with elevated levels of PHMB, an independent toxicology analysis was performed regarding the total PHMB exposure from the largest dressing and highest concentration. The conclusion of that analysis was that there was a three fold safety factor for total PHMB content. The toxicologist's report is provided in appendix 4.

Antimicrobial Efficacy

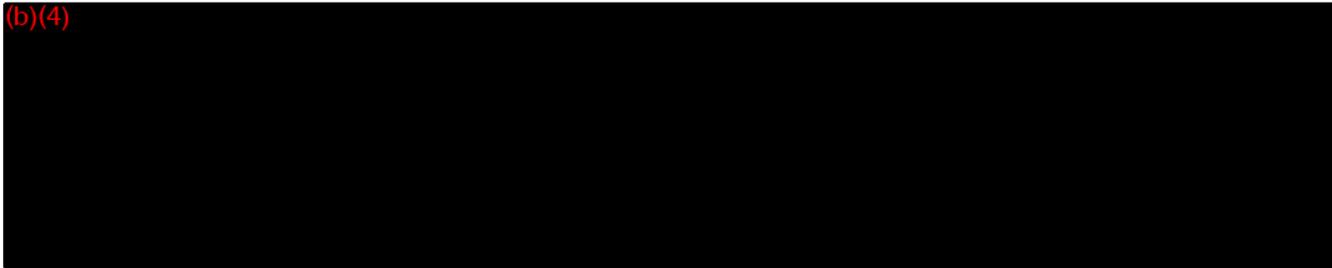
It was recognized in the risk assessment that subsets of the patients who currently receive foam dressings have wounds that do not require frequent dressing changes. In such situations, the dressings are changed on a scheduled basis, typically every seven days. In between, the dressing will be examined for fluid breakthrough periodically, but will not be changed ahead of schedule unless saturated with fluid.

Evaluation of which wounds are appropriate for this clinical protocol is beyond the scope of device design or labeling. With a traditional foam dressing, saturation is the only device related factor typically considered. It is not possible to predict when a dressing will become saturated; therefore it is not possible to provide guidance on the appropriate length of use for any dressing. Where other device specific factors are relevant, such as the duration of antimicrobial efficacy, it is appropriate to guidance on the maximum recommended use (based on the known limitations, and let established clinical protocols determine the appropriate duration of use on a case by case basis.

510(k) Premarket Notification
COPA AMD Antimicrobial Wound Dressing

Section F – Summary of Design Control Activities (continued)

To evaluate the efficacy and duration of the antimicrobial protection provided by the PHMB, COPA AMD dressings from run 11 (low PHMB) were challenged with a wide spectrum of organisms. The assay method utilized was adopted from the method reported by Parsons et al¹.



For all samples of all organisms, there was no growth from day 1 through day 7. 100% kill was achieved in every scenario. The detailed test report is provided in appendix 5.

Since 100% kill was consistently achieved, calculation of log reduction is of less value. Within the report, it is noted that for some organisms (most notably *E. faecalis*) the calculated log reductions are low on the initial days, specifically because of low/no growth in the positive controls. The untreated COPA polyurethane foam (designated run 1), because of its surface properties consistently demonstrates low level cidal properties against these organisms. All 6 organisms tested are considered appropriate challenge organisms based on clinical prevalence in wound infections, and the COPA AMD results are still considered valid because the positive control for all organisms did grow to >5 log by the 7th day. Highly adaptable organisms such as *P. aeruginosa* and *E. coli* grew rapidly from first day on the regular COPA foam.

Log Recovery, cfu/ml Test Samples Run 11

Run 11	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Organism							
<i>P. aeruginosa</i>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<i>E. coli</i>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<i>C. albicans</i>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<i>S. epidermidis</i>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<i>S. aureus</i>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<i>E. faecalis</i>	0.0	0.0	0.0	0.0	0.0	0.0	0.0

¹ Parsons D., Bowler, P., Phil M., Myles V., Jones S. Silver Antimicrobial Dressings in Wound Management: A Comparison of Antibacterial, Physical, and Chemical Characteristics. Wounds 2005; 17(8):222-232.

510(k) Premarket Notification
COPA AMD Antimicrobial Wound Dressing

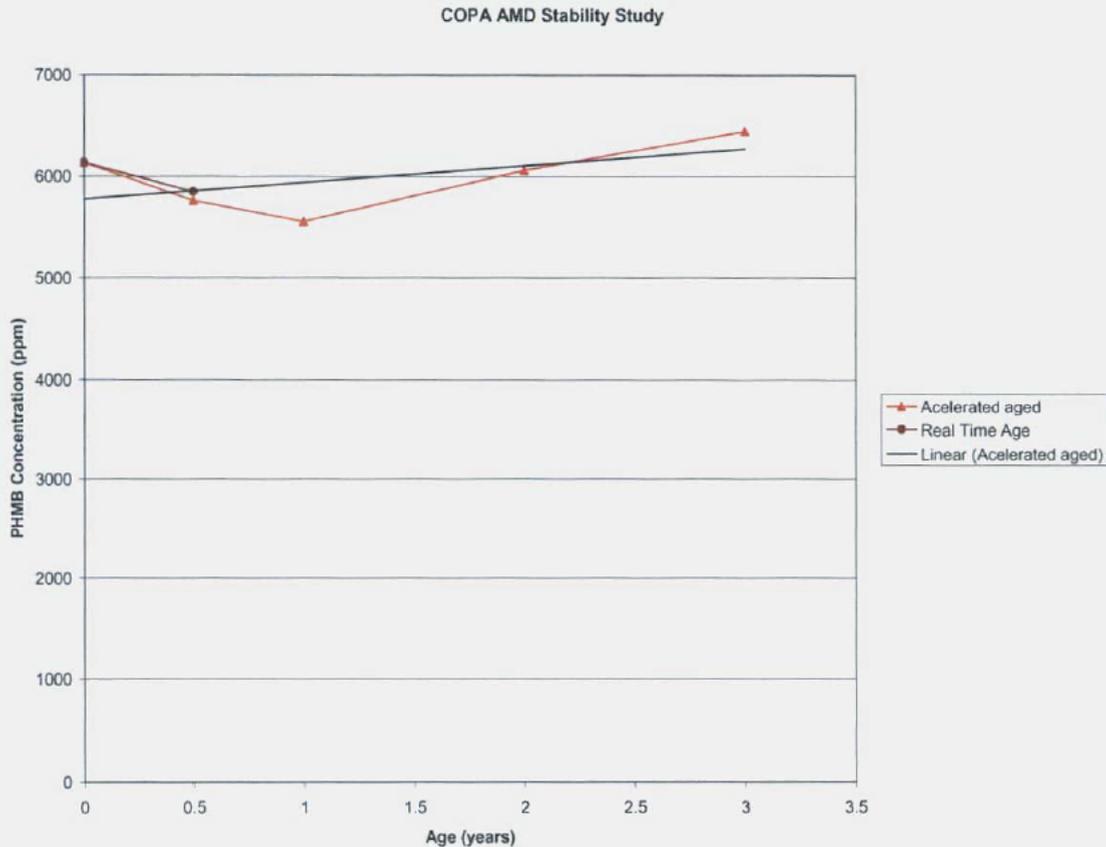
Section F – Summary of Design Control Activities (continued)

Stability

The existing COPA dressing bears a 5 year expiration date. The stability of the COPA polyurethane foam has been evaluated by accelerated age and real time studies. The focus of the stability evaluation for the COPA AMD dressing has been the PHMB component. Historically, PHMB has been found to be very stable. Since the two components individually have a proven stability history, the high loading level (run 13) was considered to be worst case.

A stability study is underway to verify that under accelerated aging [REDACTED] and in real time, the PHMB level in the dressing remains essentially constant. The graph below shows the effect of time on PHMB levels in COPA AMD dressings. Currently this study is complete through 3 years of accelerated aging, and 6 months of real time. The study will continue through 5 years.

The product would initially have an expiration date based on 3 years, with the expiration period extended to a maximum of 5 years as additional data is available.



510(k) Premarket Notification
COPA AMD Antimicrobial Wound Dressing

Appendix 1

Indications for Use Statement

Device Name:

COPA AMD antimicrobial wound dressing

Indications for Use:

COPA AMD dressings are indicated for use in management of post-surgical incisions, pressure sores, venous stasis ulcers, diabetic ulcers, donor sites, abrasions, lacerations, 1st and 2nd degree burns, dermatologic disorders, other wounds inflicted by trauma and, as a secondary dressing or cover dressing for packed wounds. COPA AMD dressings may be used on infected wounds as part of the overall medical treatment where a foam dressing is indicated for protection of the wound. The barrier function of this wound dressing may help reduce wound infections.

Please Do Not Write Below This Line – Continue On Another Page If Needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

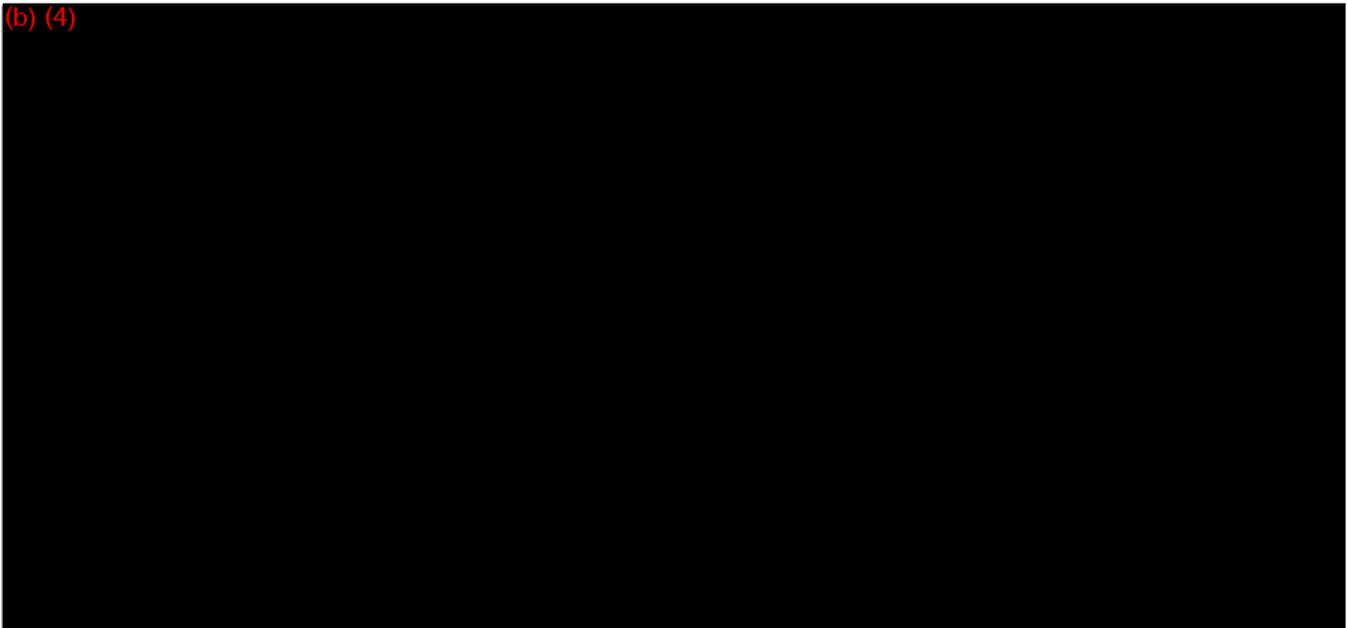
510(k) Premarket Notification
COPA AMD Antimicrobial Wound Dressing

Appendix 2

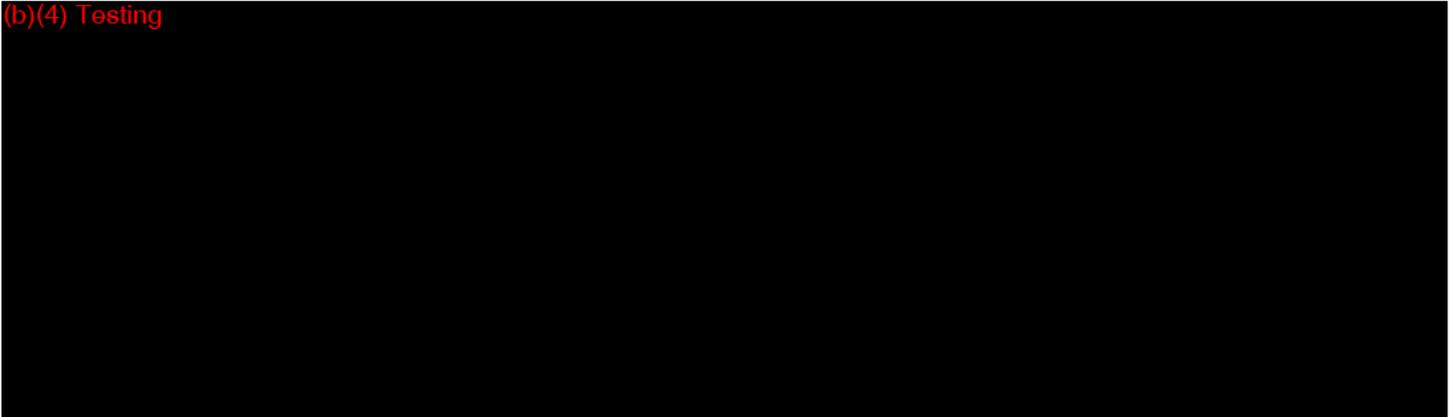
Biocompatibility Data

Biocompatibility

(b) (4)



(b)(4) Testing



196 048

TYCO HEALTHCARE / KENDALL
RESEARCH AND DEVELOPMENT

REPORT

Title: COPA™ AMD™ Antimicrobial Foam: Immersion Assay Results – Scientific Report

R&D Report Number: 055-001-MAN-07
Project Number: 2.15.85.06
Product Center: Wound Care
Report Date: February 28, 2007

Written By: *Diane McElhee* 3/22/07
Diane McElhee, Sr. Research Biologist, Bioscience R&D Date

Reviewed By: _____
Chirag B. Shah, Manager, Bioscience R&D Date

Reviewed By: _____
Hansen Swaniker, Project Leader, Wound Care R&D Date

Reviewed By: _____
David Fink, Director, Wound Care R&D Date

Reviewed By: _____
Jim Welsh, Vice President, Regulatory Affairs Date

106
244

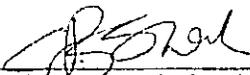
TYCO HEALTHCARE / KENDALL
RESEARCH AND DEVELOPMENT

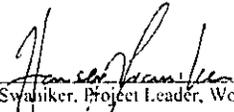
REPORT

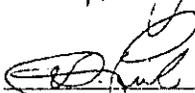
Title: COPAT[™] AMD[™] Antimicrobial Foam: Immersion Assay Results – Scientific Report

R&D Report Number: 055-001-MAN-07
Project Number: 2.15.85.06
Product Center: Wound Care
Report Date: February 28, 2007

Written By: Diane McGhee, Sr. Research Biologist, Bioscience R&D Date

Reviewed By:  3/22/07
Chirag B. Shah, Manager, Bioscience R&D Date

Reviewed By:  3/22/07
Hansen Swainiker, Project Leader, Wound Care R&D Date

Reviewed By:  3/22/07
David Fink, Director, Wound Care R&D Date

Reviewed By:  4/11/07
Jim Welsh, Vice President, Regulatory Affairs Date

Summary

This study was designed to measure the antimicrobial efficacy of sterile PHMB impregnated COPA™ AMD™ foam dressings via daily 6-log microbial challenge for 7 days. Sterile non-impregnated COPA foam dressings were used as positive and negative controls. The assay was intended to ascertain antimicrobial efficacy in a 1" disk foam dressing while submerged in 20mls of 10^6 cfu/ml phosphate buffered saline (PBS) organism suspension. The sample tubes were gently vortexed to ensure complete saturation of the foam dressings. The immersed foam dressings were incubated for 24 +/- 2 hours at 35° C +/- 2° C. After incubation, the sample tubes were gently vortexed. A 0.50ml sample aliquot was removed from each sample tube, neutralized in D/E neutralizing broth, and quantitated via standard serial dilution plate count method. After sampling, each test and control sample tube received 0.50ml of a 10^8 cfu/ml inoculate of challenge organism. Sampling and re-inoculation were performed daily for 7 days. Testing was performed in triplicate.

The sterile COPA AMD foam dressings tested were designated as Runs 11, 12, and 13. Runs 11, 12 and 13 contained 3480, 4408, and 6131 ppm of PHMB, respectively. The sterile non-impregnated COPA foam dressing was called Run 1.

The challenge organisms were *P. aeruginosa*, *E. coli*, *S. aureus*, *S. epidermidis*, *C. albicans*, and *E. faecalis*.

Run 11, 12, and 13 dressing samples exhibited remarkable efficacy against all challenge organisms. No growth (100% kill) was recovered daily for 7 days for these test samples. Run 1 dressings demonstrated slight and short-lived activity against all organisms, except *P. aeruginosa* for which no activity was exhibited. Microbial viability of daily challenge was verified using Inoculate Suspension Control. All negative controls were negative.

Under the conditions of the study, COPA AMD foam dressings proved to exhibit a broad spectrum of cidal properties against Gram-positive, Gram-negative, and fungi organisms resulting in a total kill of daily 10^6 cfu/ml challenge for 7 days.



COVER SHEET MEMORANDUM

From: Reviewer Name Sam Anpalli, Ph.D.
Subject: 510(k) Number K071371/SE
To: The Record

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

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	X	
510(k) Summary / 510(k) Statement	Attach Summary	X	
Truthful and Accurate Statement.	Must be present for a Final Decision.	X	
Is the device Class III?			X
If yes, does firm include Class III Summary?	Must be present for a Final Decision		X
Does firm reference standards? (If yes, please attach form from http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/ABB-REVISED-STANDARDS-DATA-FORM.DOC)		X	X
Is this a combination product? (Please specify category <u>4</u> , see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff - MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/ocdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Is clinical data necessary to support the review of this 510(k)?			X
Does this device include an Animal Tissue Source?			X
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	Contact OSB.		X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.		X

Regulation Number unclassified Class Dressing Product Code FRO
(*If unclassified, see 510(k) Staff)

Additional Product Codes:
Review: David Krause PRSB Nov. 14, 2007
(Branch Chief) (Branch Code) (Date)
Final Review: [Signature] DEP Dir 11/15/07
(Division Director) (Date)

**510(k) MEMORANDUM
K071371/S1&S2**

Date: November 9, 2007
From: Sam Arepalli, Ph.D.
To: File
Subject: K071371
Device: COPA AMD Antimicrobial Wound Dressing
Classification: Dressing Containing New Molecular Entity
(polyhexamethylenebiguanidine(PHMB))
Class: Unclassified
Product Code: FRO
Common Name: Dressing, Wound, Polyhexamethylenebiguanidine (PHMB)
Sponsor: Tyco Healthcare Group, LP
15 Hampshire St.
Mansfield, MA 02048
Contact: James Welsh
VP, Regulatory Affairs
508 261 8532

Recommendation:

The subject device is recommended found substantially equivalent to predicate devices.

REVIEW

*I concur
Daniel Krause
NOV. 13, 2007*

1. INTENDED USE

Subject Device:

COPA AMD dressings are indicated for use in management of post-surgical incisions, pressure sores, venous stasis ulcers, diabetic ulcers, donor sites, abrasions, lacerations, 1st and 2nd degree burns, dermatologic disorders, other wounds inflicted by trauma and, as a secondary dressing or cover dressing for packed wounds.

Predicate Device:

Kerlix™ Antimicrobial Gauze Dressing (K990530) is intended for use as a primary dressing for exudating wounds, first and second degree burns, and surgical wounds, to secure and prevent movement of a primary dressing, and as a wound packing.

Discussion of Equivalency:

The indications for use of the subject device are very similar to those of the predicate device.

2. COMPARISON OF TECHNICAL CHARACTERISTICS (DESIGN, MATERIALS, SIZES ETC.)

Subject Device:

Polyurethane (pu) foam is formed by combining a urethane pre-polymer with water. The reaction cross links the urethane, and releases carbon dioxide gas bubbles which form the foam as the polymer cross links. The process uses a substantial excess of water to assure complete cross linking and to provide consistent foam cell size. After the foam is formed, it travels through a heat tunnel to evaporate excess moisture. The dried foam is then die cut into a finished dressing. For COPA AMD plus, the foam is applied directly to the pu back sheet, no adhesives are used. For Island dressings, the die cut COPA AMD dressing is applied to an oversized adhesive back. For COPA AMD, the PHMB (polyhexamethylenebiguanide hydrochloride) is added during the foaming process so that it is thoroughly dispersed throughout the foam. The dressings will be available in sizes: 2"x2", 4"x4", 6"x6", 3 1/2"x3", and in 1" diameter.

The following table (Table 1) lists the percentages of different components of the device.

Table 1

Component Name	% by weight
(b) (4) urethane pre-polymer	40.5
USP purified water	58.6
(b) (4) (surfactant)	0.3
(b) (4) (surfactant)	0.6
Plyhexamethylene Biguanide Hydrochloride (PHMB)	5 mg per gm of foam dry weight
Adhesive border	17 mg per gm of dry foam weight

Drug Elution Testing:

The device was eluted with normal saline solution (0.9%) at 37°C. It was found that the device elutes 669 ug/g in 2 hours and as much as 1008 ug/g in 7 days.

Predicate Device:

Kerlix™ Antimicrobial Gauze Dressing (K990530) is a wound dressing consisting of gauze treated with polyhexmethylen biguanidine hydrochloride (PHMB), 0.57%.

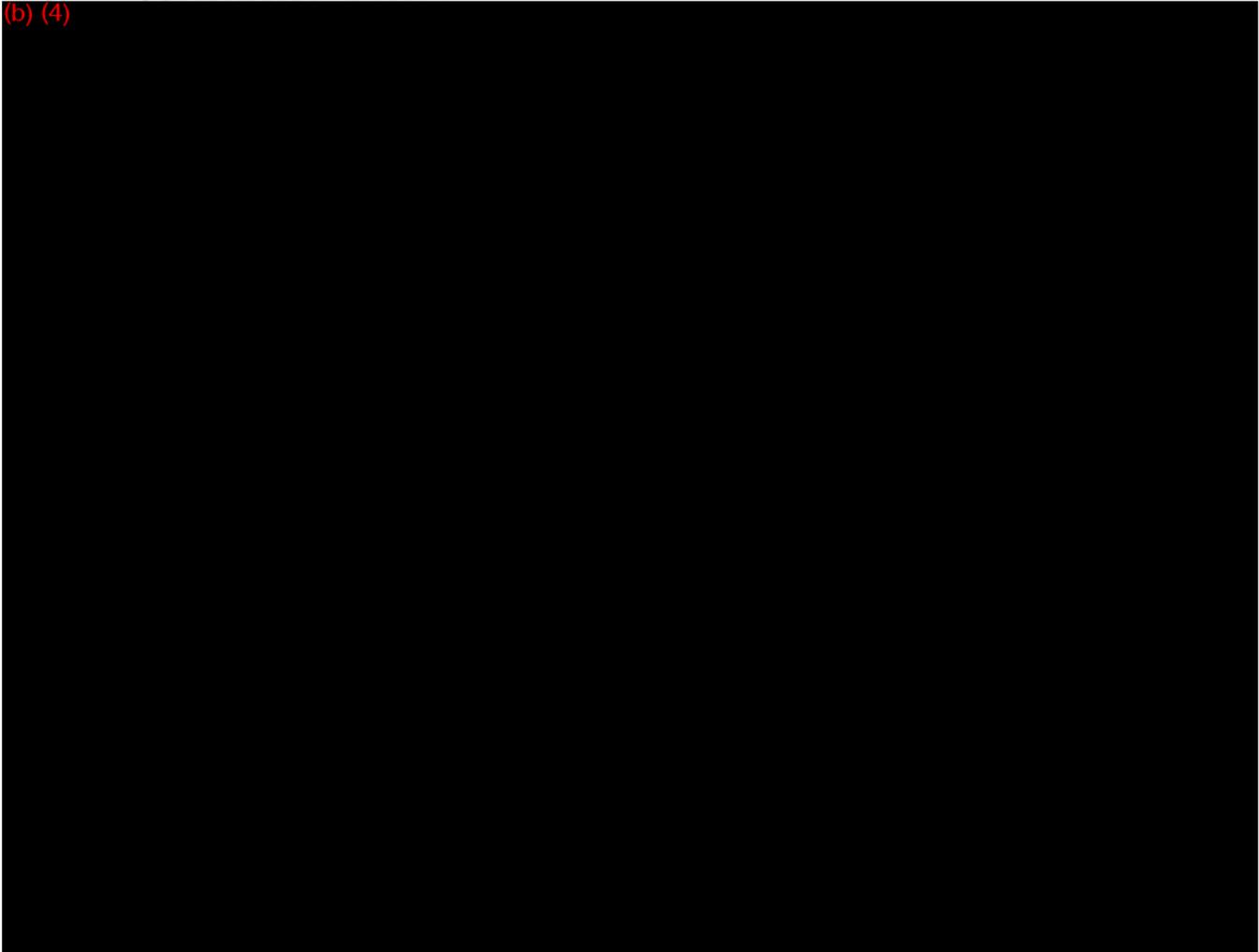
Acetic acid extraction of the device yielded approximately 1350ug/g.

Discussion of Equivalence:

Both subject device and predicate device contain polyhexmethylen biguanide hydrochloride (PHMB) at a concentration of 0.57%. The subject device is substantially equivalent to predicate devices in its formulation and the antimicrobial content.

3. COMPARATIVE DATA

(b) (4)



4. DOES THE PRODUCT CONTAIN DRUGS OR BIOLOGICALS?

Yes, the dressing contains 5 mg/g of foam dry weight (0.5% PHMB be weight).

5. STERILIZATION

Method: EtO

Validation method: ANSI/AAMI/ISO 11135:1994

SAL: 10^{-6}

Pyrogenicity Claims:

None

Packaging:

The subject devices will be packaged in a peel pouches and boxed and are sterilized by EtO

Shelf-life/Expiry Date:

The product label displays product expiration date, the shelf-life data are provided in Supplement 1. Real Time data are not provided. The sponsor was advised to delete the product expiration date from the box label.

In Supplement 2, the sponsor opted to delete the expiration date from the box label and revised copies of the box label are provided (Contact Record section and Supplement 2).

6. LABELING

The product box label displays: the product name, manufacturer' name and address, sterility condition, drug concentration and lot # (see also Supplement 2 review).

The package insert contains device description, indications for use, precautions, allergy caution statement, instructions for use.

7. CLAIMS

The device is an antimicrobial dressing.

8. ADMINISTRATIVE INFORMATION

Truthful and Accurate Statement:	See page 008
510(k) Summary:	See page 012
Indications for Use:	See page 45

9. SUMMARY

Both subject device and predicate device contain 0.5% of the antimicrobial drug, polyhexamethylene biguanide (PHMB). In case of the subject device it is impregnated into polyurethane foam whereas the predicate device is cotton gauze impregnated with PHMB.

Adequate labeling and sterilization information are provided.

The antimicrobial data were reviewed by Dr Sheila Murphey, ICDB/DAGID/ODE.

The antimicrobial used in this combination product is PHMB (polyhexmethylenebigunide). PHMB is NOT an FDA (CDRR)-approved drug and thus a new molecular entity (NME); however, the same antimicrobial was used in the predicate devices that were FDA-cleared (cleared by ODE/CDRH). This issue was discussed with the PRSB Chief, Dr. David Krause and Dr. Peter Rumm, Deputy Director, DGRND on September 26, 2007. It is concluded that because the FDA cleared other two predicate devices (under K990530 & K011941) that contain the same antimicrobial, the FDA should SE this 510(k) also. This policy should continue until the agency level decision is made on the NME issue (see Stephen Rhodes e-mail also regarding this).

The sponsor provided adequate anti-microbial (performance) data, biocompatibility and sterilization information on the subject device.

The shelf-life data (submitted in Supplement 1) is not adequate. It had no Real Time data. The sponsor was advised to delete the expiration date from the label and the revised box labels are provided in Supplement 2.

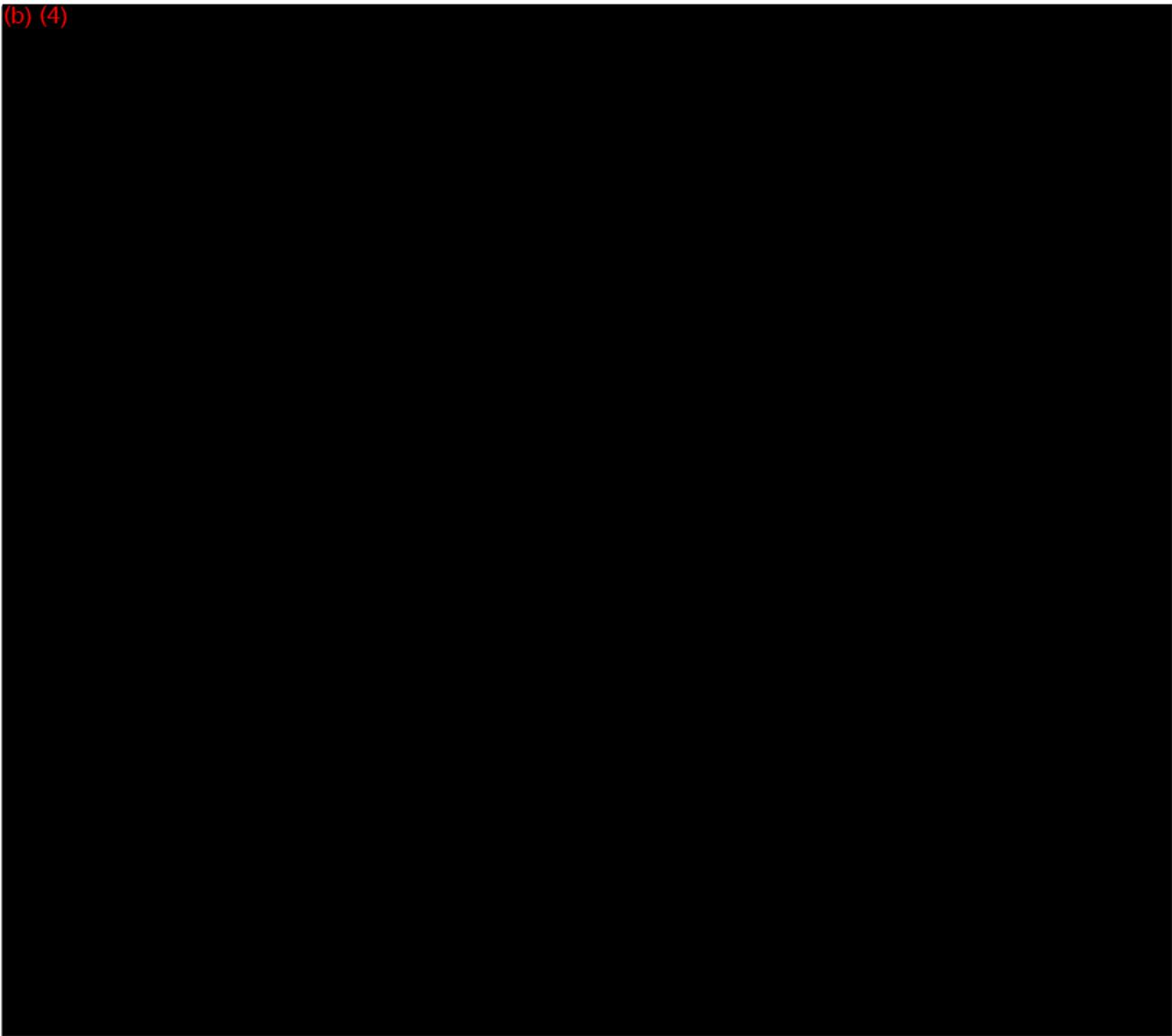
The subject device is recommended found substantially equivalent to predicate devices.

10. CONTACT RECORD

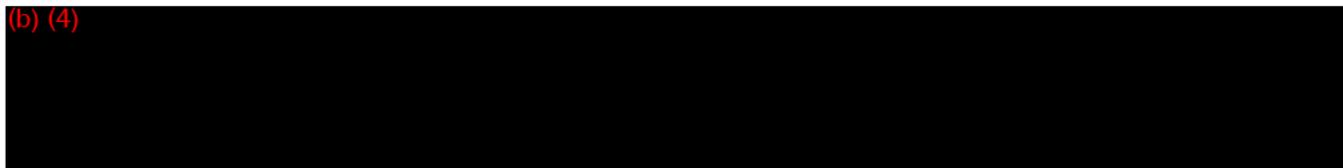
AI letters dated June 11, 2007 & October 3, 2007.

DEFICIENCIES

(b) (4)

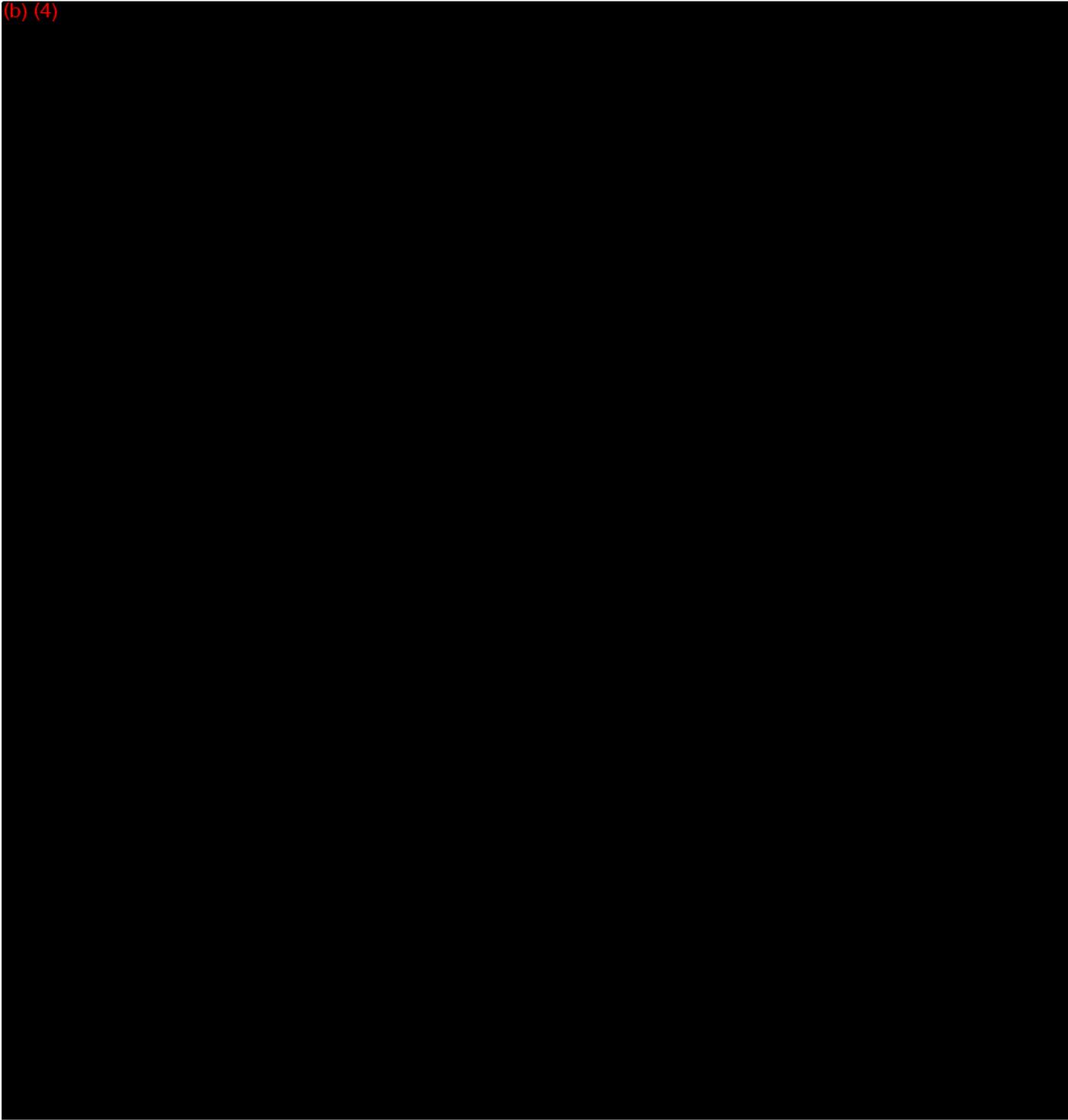


(b) (4)

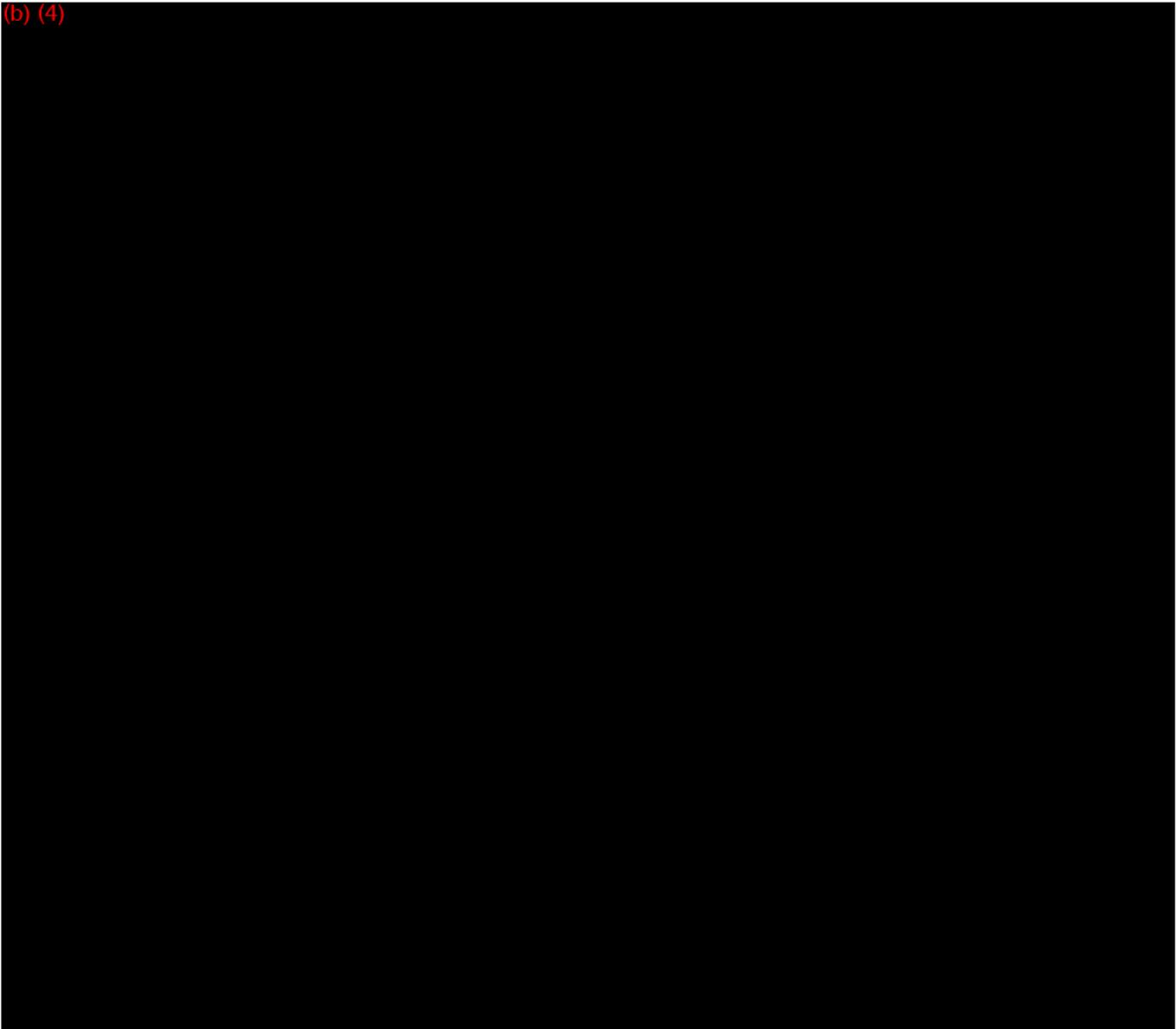
A large black rectangular redaction box covering the top portion of the page.

SUPPLEMENT 1

(b) (4)

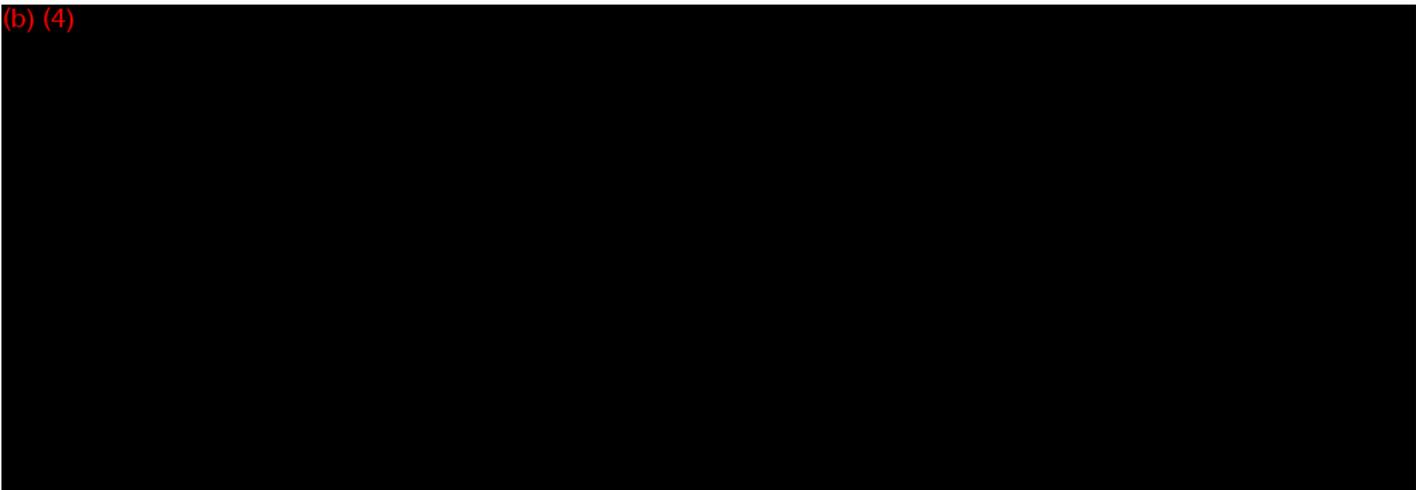
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(b) (4)

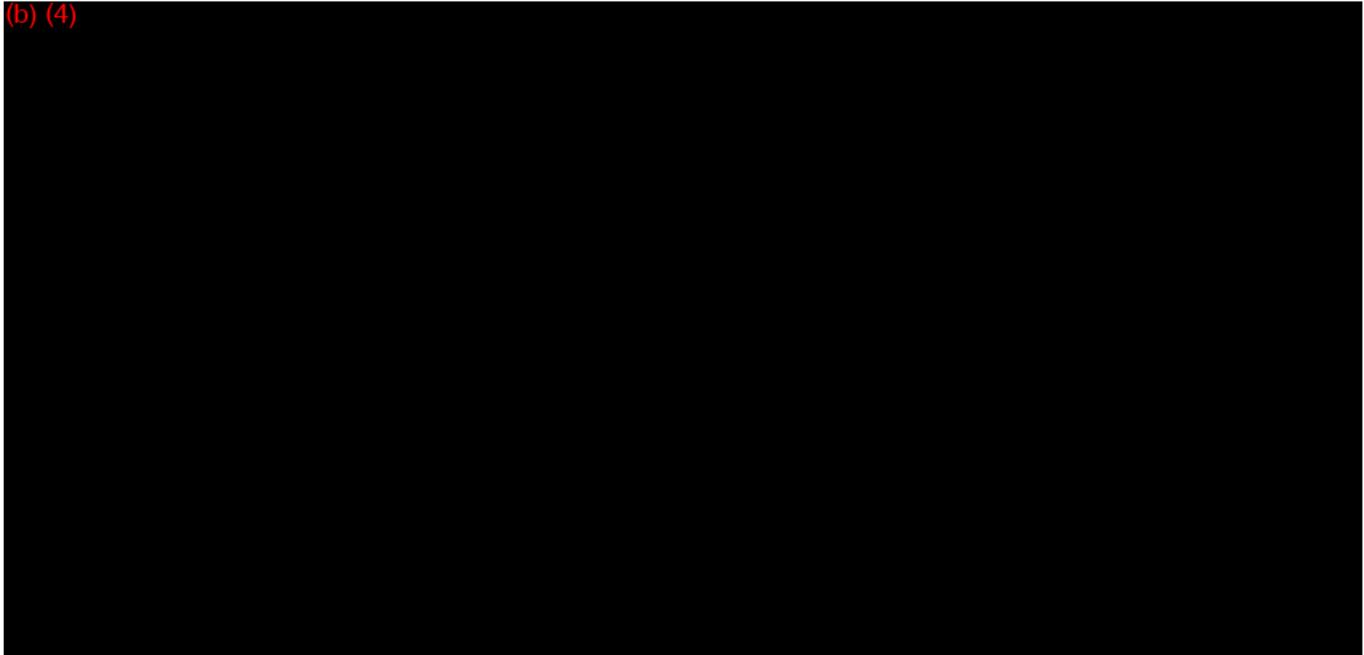


DEFICIENCIES

(b) (4)

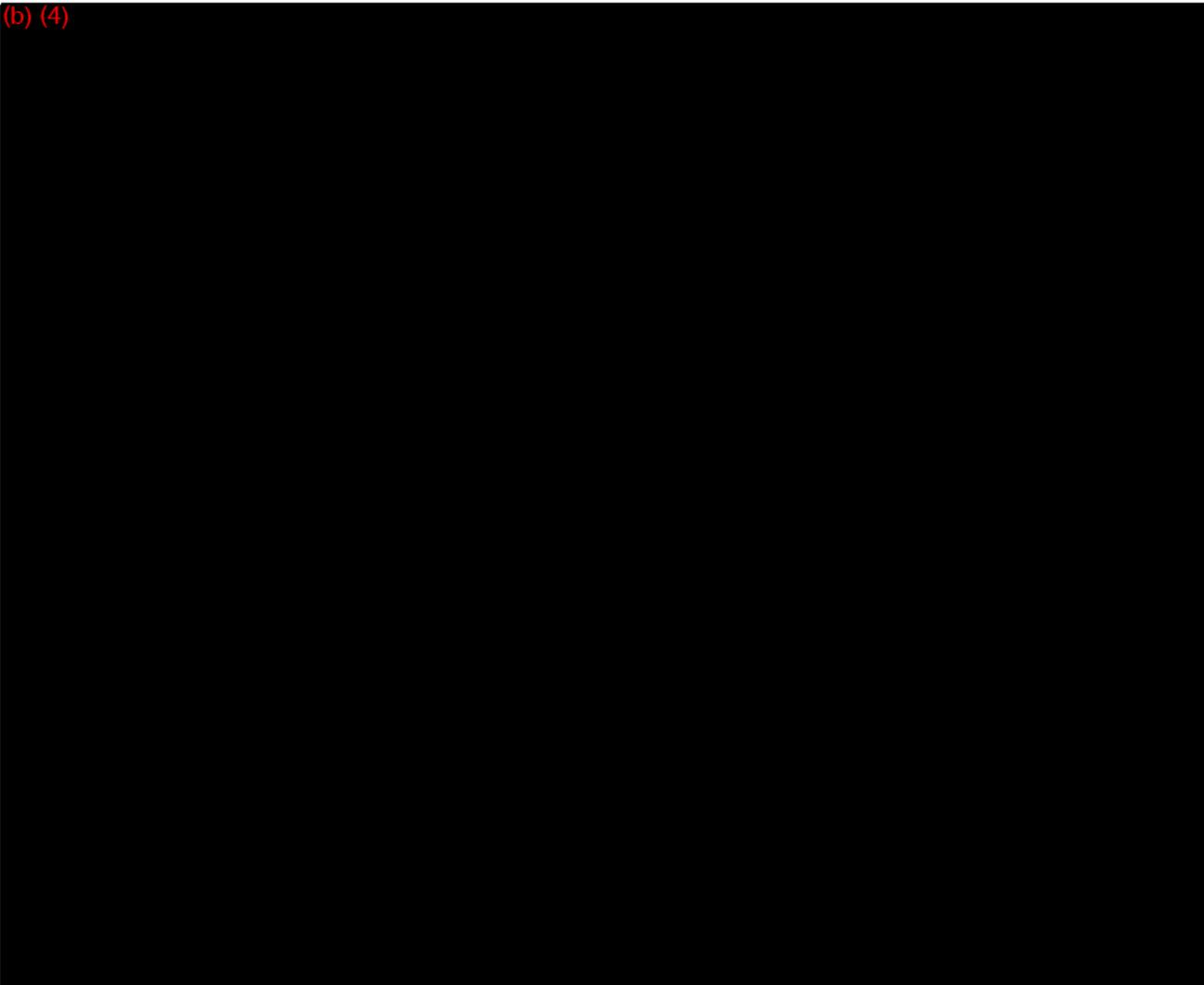


(b) (4)

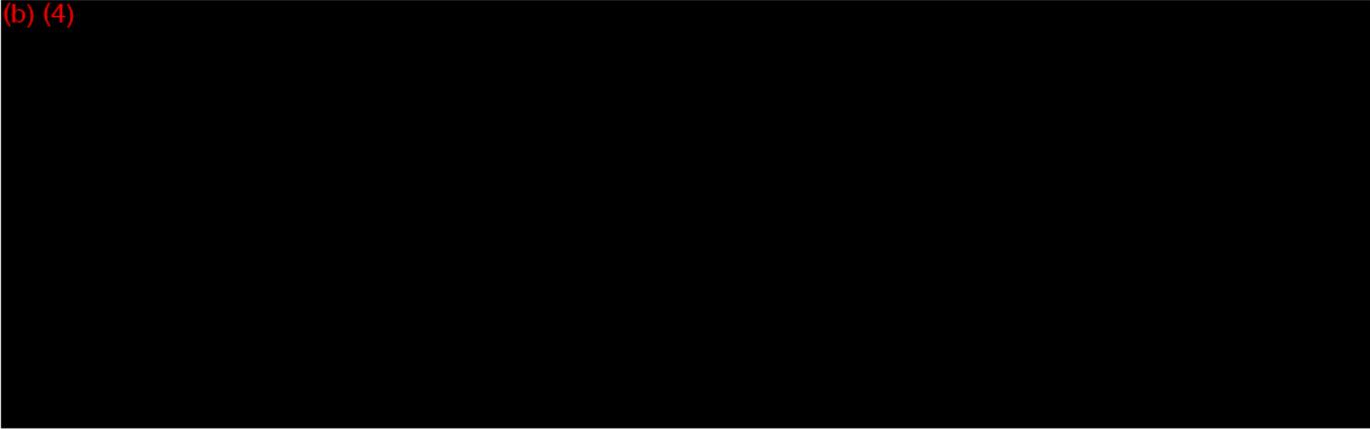


SUPPLEMENT 2

(b) (4)



(b) (4)



Sam Arepalli, Ph.D.
FDA/CDRH/ODE/DGRND/PRSB

11/13/07
Date

Arepalli, Sambasiva

From: Rhodes, Stephen
Sent: Wednesday, September 26, 2007 1:12 PM
To: Arepalli, Sambasiva; Krause, David
Cc: Rosecrans, Heather S.
Subject: RE: K071371 COPA AMD Antimicrobial Wound Dressing

Hi Sam/David,

(b) (4)

Stephen

-----Original Appointment-----

From: Arepalli, Sambasiva
Sent: Tuesday, September 25, 2007 10:28 AM
To: Hudson, Peter; Krause, David; Rhodes, Stephen; Rumm, Peter; Arepalli, Sambasiva
Subject: K071371 COPA AMD Antimicrobial Wound Dressing
When: Wednesday, September 26, 2007 12:30 PM-1:00 PM (GMT-05:00) Eastern Time (US & Canada).
Where: 350 D (Dr. Rumm's Office)

When: Wednesday, September 26, 2007 12:30 PM-1:00 PM (GMT-05:00) Eastern Time (US & Canada).
Where: 350 D (Dr. Rumm's Office)

~~*~*~*~*~*~*~*~*

(b) (4)



COVER SHEET MEMORANDUM

From: Reviewer Name Sam Medalli, PhD
Subject: 510(k) Number K071371/SI
To: The Record

Please list CTS decision code AI

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

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	X	
510(k) Summary /510(k) Statement	Attach Summary	X	
Truthful and Accurate Statement	Must be present for a Final Decision	X	
Is the device Class III?			X
If yes, does firm include Class III Summary?	Must be present for a Final Decision		X
Does firm reference standards? (If yes, please attach form from http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/ABB REVIATED STANDARDS DATA FORM.DOC)			X
Is this a combination product? (Please specify category <u>4</u> , see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)		X	
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)		X	
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Is clinical data necessary to support the review of this 510(k)?			X
Does this device include an Animal Tissue Source?			X
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	Contact OSB.		X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.		X

Regulation Number unclassified Class* Product Code FRO
(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: David Krause PRSB October 3, 2002
(Branch Chief) (Branch Code) (Date)

Final Review: _____
(Division Director) (Date)

**510(k) MEMORANDUM
K071371/S1**

Date: September 28, 2007

From: Sam Arepalli, Ph.D.

To: File

Subject: K071371

Device: COPA AMD Antimicrobial Wound Dressing

Classification: Dressing Containing New Molecular Entity
(polyhexamethylenebiguanidine(PHMB))
Class: Unclassified
Product Code: FRO

Common Name: Dressing, Wound, Polyhexamethylenebiguanidine (PHMB)

Sponsor: Tyco Healthcare Group, LP
15 Hampshire St.
Mansfield, MA 02048

Contact: James Welsh
VP, Regulatory Affairs
508 261 8532

Recommendation:
The document is put on hold pending AI.

REVIEW

*I concur
Daniel K. Paul
10/1/2007*

1. INTENDED USE

Subject Device:

COPA AMD dressings are indicated for use in management of post-surgical incisions, pressure sores, venous stasis ulcers, diabetic ulcers, donor sites, abrasions, lacerations, 1st and 2nd degree burns, dermatologic disorders, other wounds inflicted by trauma and, as a secondary dressing or cover dressing for packed wounds.

Predicate Device:

Kerlix™ Antimicrobial Gauze Dressing (K990530) is intended for use as a primary dressing for exudating wounds, first and second degree burns, and surgical wounds, to secure and prevent movement of a primary dressing, and as a wound packing.

Discussion of Equivalency:

The indications for use of the subject device are very similar to those of the predicate device.

2. COMPARISON OF TECHNICAL CHARACTERISTICS (DESIGN, MATERIALS, SIZES ETC.)

Subject Device:

Polyurethane (pu) foam is formed by combining a urethane pre-polymer with water. The reaction cross links the urethane, and releases carbon dioxide gas bubbles which form the foam as the polymer cross links. The process uses a substantial excess of water to assure complete cross linking and to provide consistent foam cell size. After the foam is formed, it travels through a heat tunnel to evaporate excess moisture. The dried foam is then die cut into a finished dressing. For COPA AMD plus, the foam is applied directly to the pu back sheet, no adhesives are used. For Island dressings, the die cut COPA AMD dressing is applied to an oversized adhesive back. For COPA AMD, the PHMB (polyhexamethylenebiguanide hydrochloride) is added during the foaming process so that it is thoroughly dispersed throughout the foam. The dressings will be available in sizes: 2"x2", 4"x4", 6"x6", 3 1/2"x3", and in 1" diameter.

The following table (Table 1) lists the percentages of different components of the device.

Table 1

Component Name	% by weight
(b) (4) urethane pre-polymer	40.5
USP purified water	58.6
(b) (4) (surfactant)	0.3
(b) (4) surfactant)	0.6
Plyhexamethylene Biguanide Hydrochloride (PHMB)	5 mg per gm of foam dry weight
Adhesive border	17 mg per gm of dry foam weight

Drug Elution Testing:

The device was eluted with normal saline solution (0.9%) at 37°C. It was found that the device elutes 669 ug/g in 2 hours and as much as 1008 ug/g in 7 days.

Predicate Device:

Kerlix™ Antimicrobial Gauze Dressing (K990530) is a wound dressing consisting of gauze treated with polyhexmethylen biguanidine hydrochloride (PHMB), 0.57%.

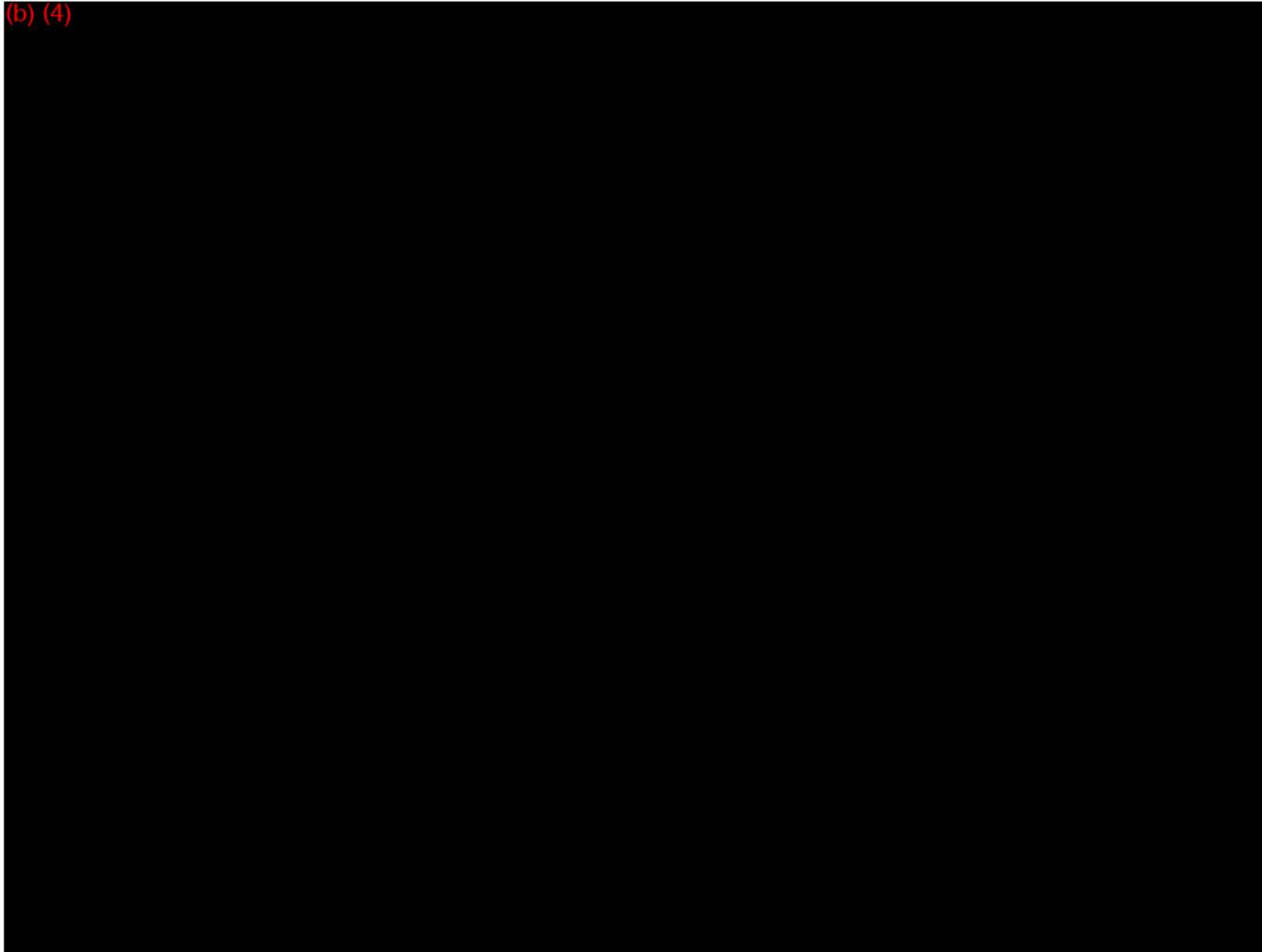
Acetic acid extraction of the device yielded approximately 1350ug/g.

Discussion of Equivalence:

Both subject device and predicate device contain polyhexmethylene biguanide hydrochloride (PHMB) at a concentration of 0.57%. The subject device is substantially equivalent to predicate devices in its formulation and the antimicrobial content.

3. COMPARATIVE DATA

(b) (4)



4. DOES THE PRODUCT CONTAIN DRUGS OR BIOLOGICALS?

Yes, the dressing contains 5 mg/g of foam dry weight (0.5% PHMB be weight).

5. STERILIZATION

Method: EtO

Validation method: ANSI/AAMI/ISO 11135:1994

SAL: 10^{-6}

Pyrogenicity Claims:

None

Packaging:

The subject devices will be packaged in a peel pouches and boxed and are sterilized by EtO

Shelf-life/Expiry Date:

The product label displays product expiration date, the shelf-life data are provided in Supplement 1.

6. LABELING

The product box label displays: the product name, manufacturer' name and address, sterility condition, drug concentration, lot #, product expiration date.

The package insert contains device description, indications for use, precautions, instructions for use.

7. CLAIMS

The device is an antimicrobial dressing.

8. ADMINISTRATIVE INFORMATION

Truthful and Accurate Statement:	See page 008
510(k) Summary:	See page 012
Indications for Use:	See page 45

9. SUMMARY

Both subject device and predicate device contain 0.5% of the antimicrobial drug, polyhexamethylene biguanide (PHMB). In case of the subject device it is impregnated into polyurethane foam whereas the predicate device is cotton gauze impregnated with PHMB.

Adequate labeling and sterilization information are provided.

The antimicrobial data were reviewed by Dr Sheila Murphey, ICDB/DAGID/ODE.

The antimicrobial used in this combination product is PHMB (polyhexmethylenebigunide). PHMB is NOT an FDA (CDRR)-approved drug and thus a new molecular entity (NME); however, the same antimicrobial was used in the predicate devices that were FDA-cleared (cleared by ODE/CDRH). This issue was discussed with the PRSB Chief, Dr. David Krause and Dr. Peter Rumm, Deputy Director, DGRND on September 26, 2007. It is concluded that because the FDA cleared other two predicate devices (under K990530 & K011941) that contain the same antimicrobial, the FDA should SE this 510(k) also. This policy should continue until the agency level decision is made on the NME issue (see Stephen Rhodes e-mail also regarding this).

The sponsor provided adequate anti-microbiological (performance) data, biocompatibility and sterilization information on the subject device.

The shelf-life data (submitted in Supplement 1) and the labeling information are NOT adequate.

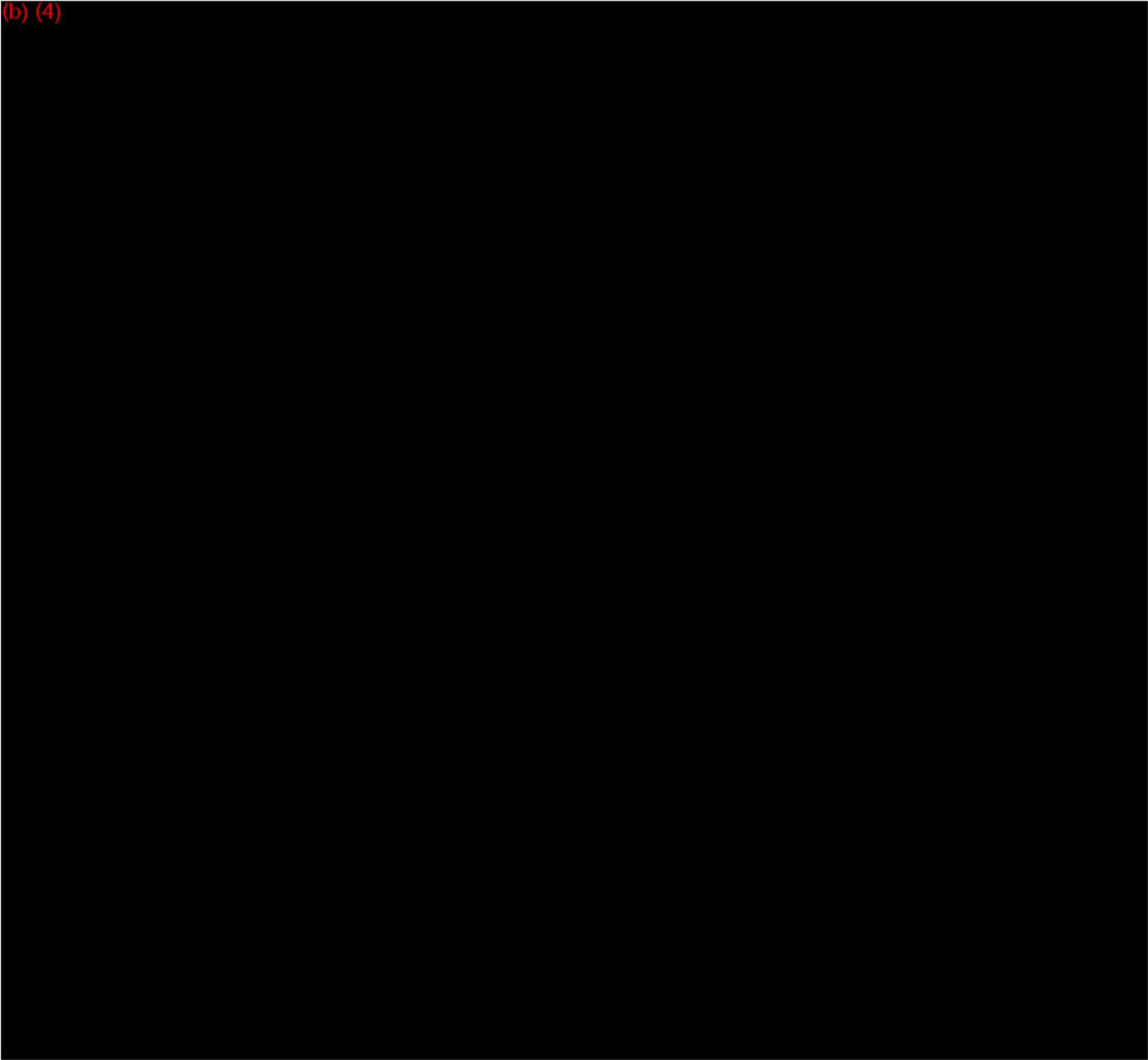
The document is put on hold pending AI.

10. CONTACT RECORD

AI letter is sent to sponsor.

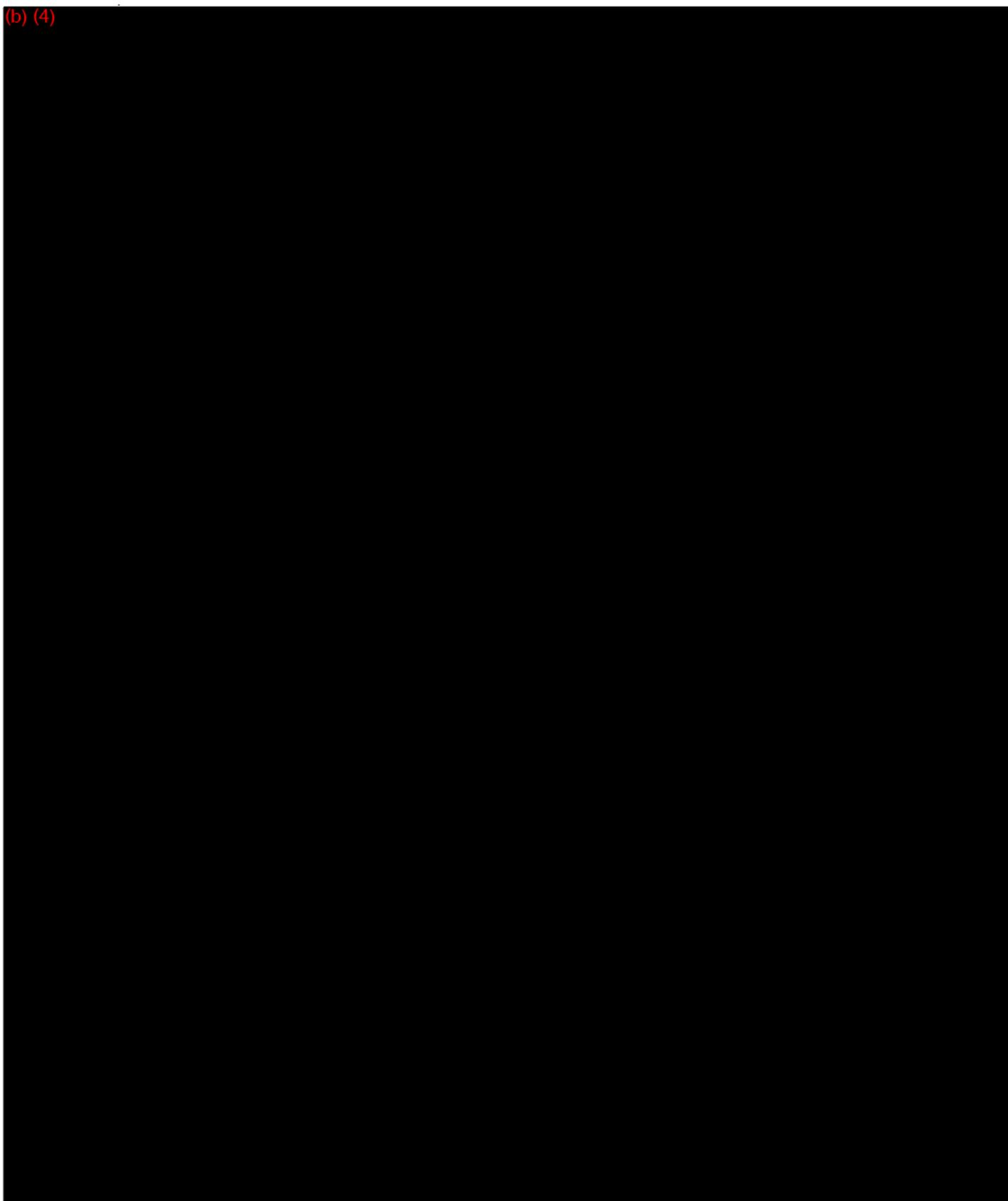
DEFICIENCIES

(b) (4)

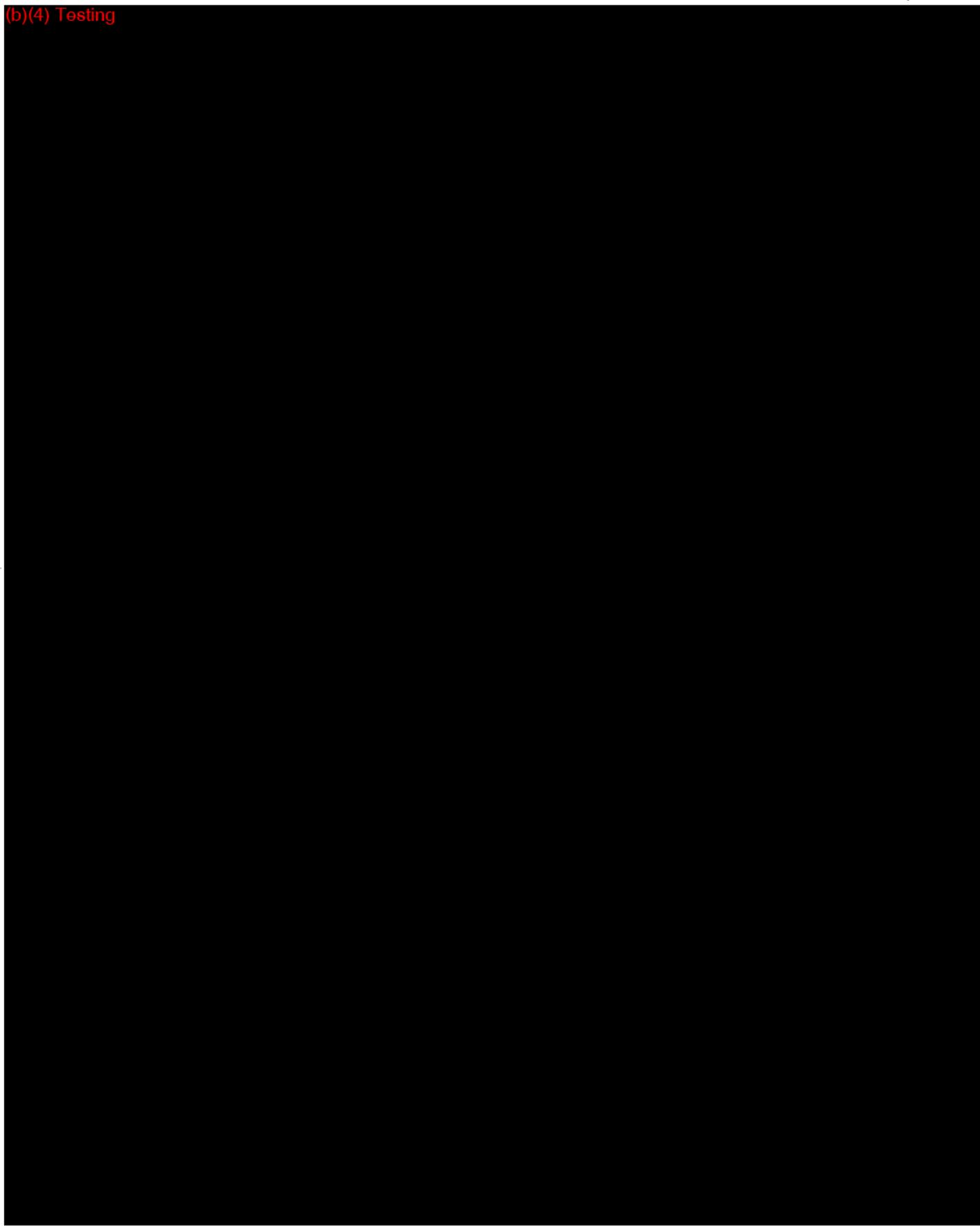


SUPPLEMENT 1

(b) (4)



(b)(4) Testing



(b) (4)



SArepalli
Sam Arepalli, Ph.D.
FDA/CDRH/ODE/DGRND/PRSB

10/1/07
Date

Consultation Review

Document Number: K071371/S001

Device Name: COPA AMD Antimicrobial Foam Dressings

Sponsor: Kendall/Tyco Healthcare Group LP

Reviewer: Sheila A. Murphey, MD

Branch Chief, Infection Control Devices Branch

Date: September 29, 2007

Kendall, a Division of Tyco Healthcare LP, wishes to introduce into interstate commerce the COPA AMD Antimicrobial Foam Dressings which contain 0.5% Polyhexamethylene Biguanide Hydrochloride (PHMB). The dressings consist of polyurethane foam, originally cleared as Curafoam in K946269 and now marketed as COPA dressings. The only difference is the addition of PHMB at a concentration of 0.5% (5mg/gm dry weight foam). When in absorbent mode, the COPA AMD dressings are stated to have 0.33 mg PHMD/mL liquid absorption capacity. Eight different size/shape configurations of the dressings are listed in this submission. They range in size from 1 inch to 6 inch dimensions and are sold as foam pads, foam pads with a liquid impervious film backsheet and as foam pads with a liquid impervious backsheet which includes an adhesive border. They are sold in individual sterile pouches packaged in multiunit boxes.

The Infection Control Devices Branch was not asked to review this submission during its first review cycle. We are now asked to determine whether the submitted microbiology performance data is adequate to support the claims made for this device.

Two different versions of the Indications for Use statement appear in the material sent to me for review. One says "COPA AMD dressings are indicated for use in management of post-surgical incisions, pressure sores, venous stasis ulcers, diabetic ulcers, donor sites, abrasions, lacerations, 1st and 2nd degree burns, dermatologic disorders, other wounds inflicted by trauma and, as a secondary dressing or cover dressing for packed wounds".

A second version adds to the above statement "COPA AMD dressings may be used on infected wounds as part of the overall medical treatment where a foam dressing is indicated for protection of the wound. ***The barrier function of this wound dressing may help reduce wound infections.***

This last sentence is not supported by any data in this submission. A claim to "help reduce wound infections" can only be supported by data from a controlled clinical trial on wound infections. Either the sponsor should provide such clinical data or this claim should be removed from the submission. Note that this statement also appears in the "Section A General Device Summary" in "Indications/Intended Use" and is equally problematic there. It appears again in the Table in Section E comparing the COPA AMD Dressing to its predicate devices. It remains equally problematic here as well. I note that a similar claim appears listed for the Excilon AMD Dressing (K011941). However, if no clinical data is presented to support it, this claim to "help reduce wound infections" should not be allowed for the COPA AMD Dressings.

The initial description of the COPA AMD Dressings contains the statement "By limiting the microbial growth in wound exudates, the bioburden load on healing tissue is minimized". The performance data submitted for review contains only test results addressing the ability of the COPA AMD Dressings to directly inhibit microbial growth. No data addressing quantitative microbial loads in actual wound exudates is presented. This claim is not supported by the submitted performance data. Either the sponsor should provide clinical data to support this claim or it should be withdrawn by the sponsor.

It should be noted that not all of the package labels submitted fully identify the added antimicrobial agent. Some packaging only says "0.5% PHMB", although one label does identify the material as 0.5% Polyhexamethylene biguanide hydrochloride. I recommend that all product labels fully identify the contained antimicrobial agent. None of the labels warn against the possibility of hypersensitivity/allergic reactions to the antimicrobial agent. Unless the sponsor can present data to justify the lack of such a caution statement, I recommend that it be added to all of the labeling of the device.

The dressings are labeled "single use".

The method of incorporation of PHMB into the COPA AMD Dressings is not provided in the material which I received. The specifications for the PHMB in the device are not provided except for a passing mention in section F which mentions a "specification nominal of 0.5% (5000 ppm)". The specifications and their range should be provided for review along with data addressing the release/leach off rate of PHMB from the dressing into the wound.

The antimicrobial performance testing data for the COPA AMD Dressings is presented in Appendix 1. The organization is rather confusing. However, the assays used are quantitative kill curves performed in broth media and using inocula of 10^6 test organisms along with inoculum controls and untreated foam dressing controls. Once inoculated, the test vessel is sampled (b) (4) he removed (b) (4) was placed into neutralizing medium (to inactivate the PHMB) and then dilution cultures were prepared in triplicate. The process included replacement of the removed aliquot (b) (4) (b) (4). This is a satisfactory test method. The organisms tested were ATCC strains of *E. coli*, *S. aureus*, *P. aeruginosa*, *C. albicans*, *S. epidermidis* and *E. faecalis*.

The narrative report described the results of "Runs 11, 12 and 13" as well as run 1. However, actual data were presented only for Run 11. Appendix 1 describes the actual test materials evaluated as having concentrations of PHMB which differ significantly from the 0.5% (5000 ppm) which is stated in the devices description. The reason for this difference is not described in Appendix 1; for that information, one must turn back to Section F. In Section F, the test material used in "Run 11" is described as having a PHMB level of (b) (4) whereas the COPA AMD Dressing which is the subject of this submission is described as having a PHMB concentration of 0.5% PHMB (5mg/gm dry weight foam). The stated justification for this failure to use the dressing which is the subject of the submission is stated as follows. "One overlying risk is that certain key parameters are directly tied to PHMB concentration and, like any process, there will be some level of variation in the level of PHMB in an individual dressing. To address

this, special runs of COPA AMD were produced to provide a realistic estimate of worst case process variation in PHMB concentration".

It is rather disturbing that the sponsor believes that there may actually be a chance that the PHMB concentration in the COPA AMD Dressing will be over 30% lower than the nominal concentration of PHMB. The sponsor should be asked, as suggested above, to state the method of incorporation of PHMB into the COPA AMD dressings and the allowable specifications for its concentration.

It is true that the data obtained from the testing performed in "Run 11" is actually "worst case" with respect to the dressing which is the subject of this submission. However, it is unusual to evaluate device performance in this manner. "Run 12" was performed with a material said to have a PHMB concentration of (b) (4) and "Run 13" was performed on test material with a PHMB concentration of (b) (4). Only the data for Run 11 is provided in detail.

The significant results of Run 11 can be summarized quickly; for all 6 test organisms, the subcultures on days 1 through 7 showed no recovered organisms while the inoculum controls remained at 10^6 to 10^7 organisms. The foam dressing controls, which contained no PHMB, served as a useful second set of controls since these subcultures were also inoculated into the neutralizing media used to neutralize the PHMB. Gram negative bacillary growth in the presence of the untreated foam dressings was equivalent to the untreated inoculum controls. The untreated foam, however, modestly inhibited the growth of the gram positive microbes tested for 4 to 5 days.

The inhibition of gram positive microbes by the COPA foam dressings which do not contain PHMB is interesting but does not change the evaluation of the PHMB-containing dressings. The sponsor did present the Run 11 data in a format which subtracted the value of the antimicrobial activity of the plain foam dressing from that of the PHMB-containing dressing. The display results in an apparent antimicrobial activity of less than 4 log inoculum reduction for the COPA AMD dressings against gram positive organisms. However, I do not consider this to be a reasonable calculation, since the plain foam dressing was clearly not an inactive "control".

These data show that a foam dressing with a concentration of PHMB considerably lower than the nominal concentration of PHMB in the dressing which is the subject of this submission can achieve a greater than 4 log reduction from a 6 log inoculum against *E. coli*, *P. aeruginosa*, *S. aureus*, *S. epidermidis*, *E. faecalis* and *C. albicans*. The summary for Appendix 1 states that Run 12 and Run 13 also showed no recovery of the 6 test organisms when tested against the other two concentrations of PHMB, one of which is higher than the nominal concentration of PHMB in the COPA AMD dressing which is the subject of this submission.

The antimicrobial activity performance testing data described above was apparently not performed on devices at the end of the stated shelf life. A short, summary description of antimicrobial performance testing on aged product is included in the material sent for review. Apparently, this testing has been performed on devices subjected to accelerated aging at (b) (4) relative humidity at the equivalents of 3 years and 5 years (b) (4). The

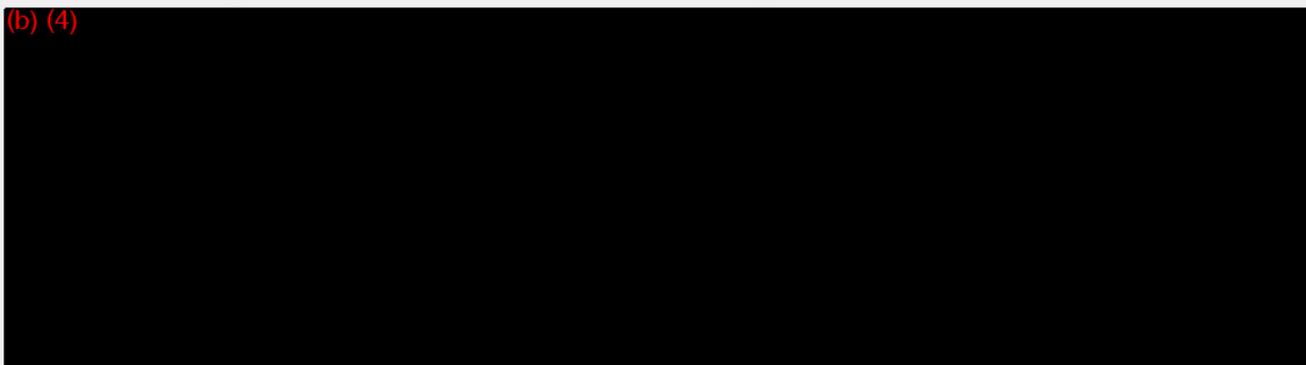
actual test data is not provided, only a narrative summary. Testing was apparently done on the modified product described above (with PHMB concentrations of (b) (4) ppm respectively). Apparently, only *P. aeruginosa* antimicrobial activity was evaluated. The justification for this is stated to be "it demonstrated the highest growth rates in the control groups and therefore would have been the most difficult to kill". This is not logical. The growth rate of an organism in the absence of an antimicrobial agent does not necessarily predict the activity of the agent against that organism. The sponsor should demonstrate the antimicrobial activity of the COPA AMD Dressing at the end of its claimed shelf life against all of the organisms against which it claims antimicrobial activity. The complete data should be presented for review by the agency just as it was presented for unaged product in Appendix 1. The sponsor need not repeat the testing for *P. aeruginosa*, but merely submit the complete data set. It should be noted that the "Specification" for antimicrobial activity listed over the data summary for *P. aeruginosa* of ≥ 2 log reduction for 7 days is not adequate (apparently activity against *P. aeruginosa* was on the order of 6 logs). The criterion for antimicrobial activity should be a 4 log reduction in inoculum in order for aged product to be equivalent to unaged product.

In Summary,

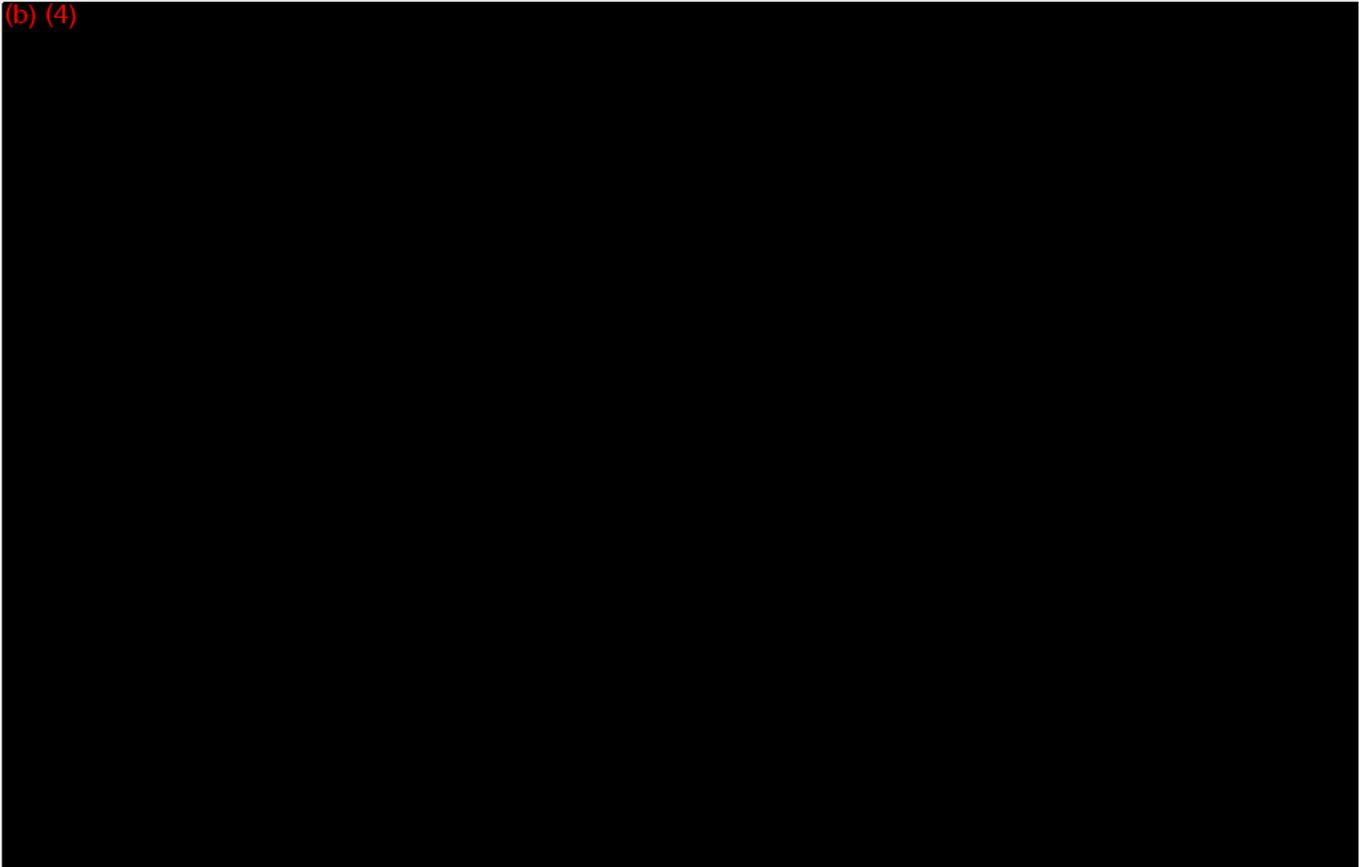
1. The antimicrobial activity performance test data included in the material given to me demonstrate that unaged "COPA AMD Dressings" which contain only (b) (4) and are not the dressing which is the subject of this submission do demonstrate significant antimicrobial activity against *E. coli*, *P. aeruginosa*, *S. aureus*, *S. epidermidis*, *C. albicans* and *E. faecalis*, enough to support the claim of antimicrobial activity sought.
2. The sponsor has not demonstrated complete antimicrobial activity in its device at the end of its proposed shelf life.
3. The data submitted for consultation review do not support two clinical claims made by the sponsor.
4. Several product labels lack a complete description of the antimicrobial agent and all lack a caution statement for hypersensitivity/allergic reactions.

The following deficiencies should be conveyed to the sponsor:

(b) (4)



(b) (4)



Sheila A. Murphey, MD
Branch Chief, Infection Control Devices Branch
September 29, 2007

6/6/07

From: Reviewer(s) - Name(s) Sam Antallio, Ph.D. DK

Subject: 510(k) Number K071371

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

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- | | | |
|---|---|--|
| Is this device subject to Section 522 Postmarket Surveillance? | <input type="checkbox"/> YES | <input checked="" type="checkbox"/> NO |
| Is this device subject to the Tracking Regulation? | <input type="checkbox"/> YES | <input checked="" type="checkbox"/> NO |
| Was clinical data necessary to support the review of this 510(k)? | <input checked="" type="checkbox"/> YES | <input checked="" type="checkbox"/> NO |
| Is this a prescription device? | <input checked="" type="checkbox"/> YES | <input type="checkbox"/> NO |
| Was this 510(k) reviewed by a Third Party? | <input type="checkbox"/> YES | <input checked="" type="checkbox"/> NO |
| Special 510(k)? | <input type="checkbox"/> YES | <input checked="" type="checkbox"/> NO |
| Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers | <input type="checkbox"/> YES | <input checked="" type="checkbox"/> NO |

- Truthful and Accurate Statement Requested Enclosed
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices *N/A*
- The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) 4

Animal Tissue Source YES NO Material of Biological Origin YES NO

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

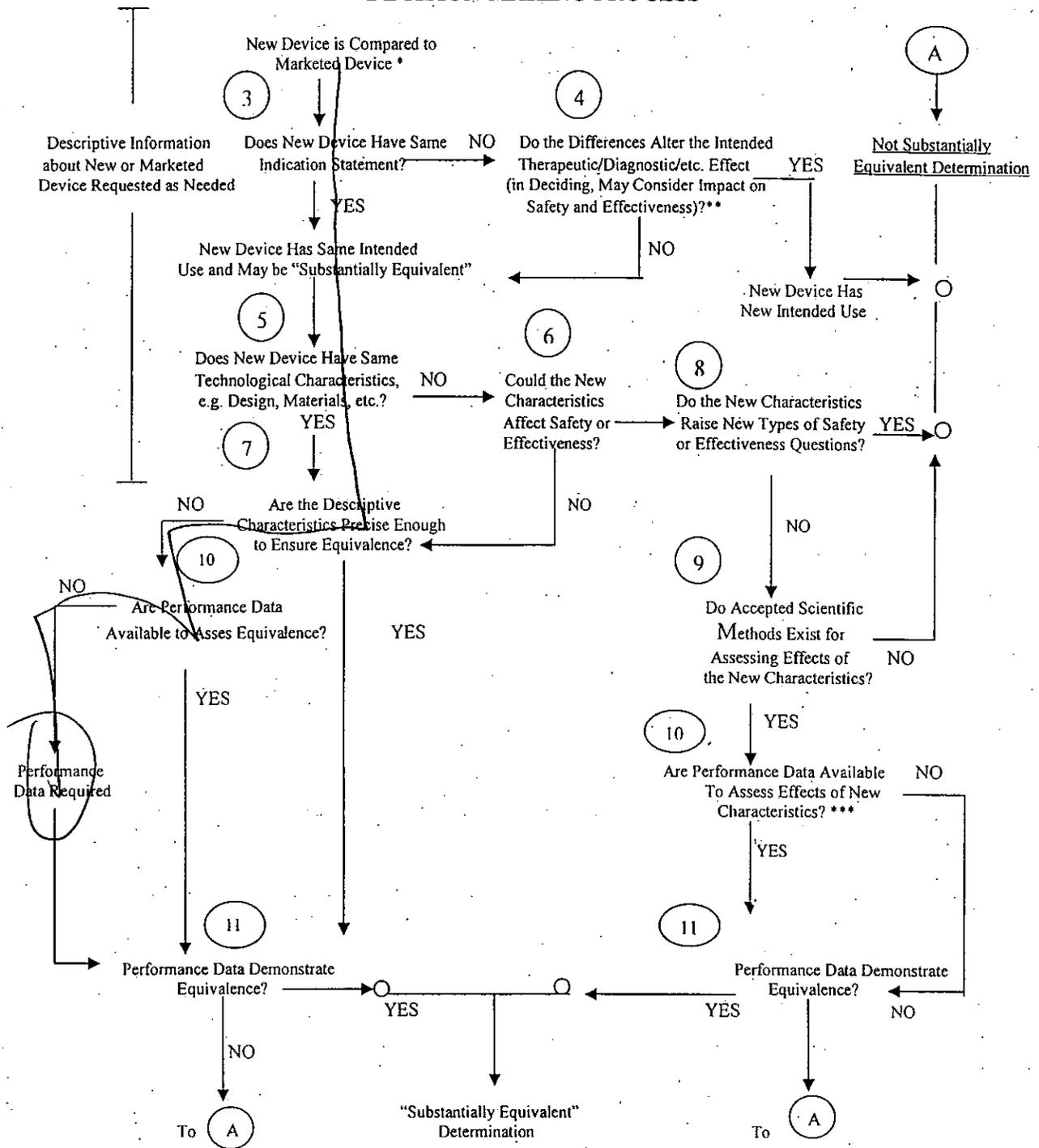
- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Predicate Product Code with class: FRO, Dressing, unclassified Additional Product Code(s) with panel (optional):

Review: Anastacia M Bilek FRSR 6/11/07
(Branch Chief) (Branch Code) (Date)

Final Review: _____
(Division Director) (Date)

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



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

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

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Internal Administrative Form

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

**SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS**

510(k) Number: K071371

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

- Special 510(k) - Do Sections 1 and 2
- Abbreviated 510(k) - Do Sections 1, 3 and 4
- Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510] Manual.	✓	
Table of Contents.	✓	
Truthful and Accurate Statement.	✓	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510] Manual.	✓	
Statement of Indications for Use that is on a separate page in the premarket submission.	✓	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate.	✓	
510(k) Summary or 510(k) Statement.	✓	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	✓	
Identification of legally marketed predicate device. *		
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]		
Class III Certification and Summary. **	MA	
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	N/A	
510(k) Kit Certification ***	MA	

* - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

MA

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.		
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

M/D

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard, which is posted with the 510(k) boilers on the H drive.]		

For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device <u>and</u> any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

- * - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	✓	
b) Sterilization and expiration dating information:	✓	
i) sterilization process	✓	
ii) validation method of sterilization process	✓	
iii) SAL	✓	
iv) packaging	✓	
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:		

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the "Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening Yes No

Reviewer: SP [Signature]

Concurrence by Review Branch: _____

Date: _____

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>

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

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 071371

Reviewer: Sam A. Gallo

Division/Branch: DGRND/P288

Device Name: OPA AMD Antimicrobial Wound Dressing

Product To Which Compared (510(K) Number If Known): K990520

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

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

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

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

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

ATTACH ADDITIONAL SUPPORTING INFORMATION

**510(k) MEMORANDUM
K071371**

Date: June 6, 2007

From: Sam Arepalli, Ph.D.

To: File

Subject: K071371

Device: COPA AMD Antimicrobial Wound Dressing

Classification: Dressing Containing New Molecular Entity
(polyhexamethylenebiguanidine(PHMB))
Class: *Unclassified*
Product Code: *FRO*

Common Name: Dressing, Wound, Polyhexamethylenebiguanidine (PHMB)

Sponsor: Tyco Healthcare Group, LP
15 Hampshire St.
Mansfield, MA 02048

Contact: James Welsh
VP, Regulatory Affairs
508 261 8532

Recommendation:

The document is put on hold pending AI.

REVIEW

1. INTENDED USE

Subject Device:

COPA AMD dressings are indicated for use in management of post-surgical incisions, pressure sores, venous stasis ulcers, diabetic ulcers, donor sites, abrasions, lacerations, 1st and 2nd degree burns, dermatologic disorders, other wounds inflicted by trauma and as a secondary dressing or cover dressing for packed wounds. COPA AMD dressings may be used on infected wounds as part of the overall medical treatment where a foam dressing is

indicated for protection of the wound. The barrier function of this wound dressing may help reduce wound infections.

Predicate Device:

Kerlix™ Antimicrobial Gauze Dressing (K990530) is intended for use as a primary dressing for exudating wounds, first and second degree burns, and surgical wounds, to secure and prevent movement of a primary dressing, and as a wound packing.

Discussion of Equivalency:

The indications for use of the subject device are different from those of the predicate device.

Question:

The indications for use (IFU) of your device are substantially different from those of the predicate device, Kerlix™ Antimicrobial Gauze Dressing and your device IFU statement contains additional indication, “may be used on infected wounds and the barrier function of this wound dressing may help reduce wound infections”. Please either delete this additional statement from the device IFU statement or provide clinical data to support these indications for use.

2. COMPARISON OF TECHNICAL CHARACTERISTICS (DESIGN, MATERIALS, SIZES ETC.)

Subject Device:

Polyurethane (pu) foam is formed by combining a urethane pre-polymer with water. The reaction cross links the urethane, and releases carbon dioxide gas bubbles which form the foam as the polymer cross links. The process uses a substantial excess of water to assure complete cross linking and to provide consistent foam cell size. After the foam is formed, it travels through a heat tunnel to evaporate excess moisture. The dried foam is then die cut into a finished dressing. For COPA AMD plus, the foam is applied directly to the pu back sheet, no adhesives are used. For Island dressings, the die cut COPA AMD dressing is applied to an oversized adhesive back. For COPA AMD, the PHMB (polyhexamethylenebiguanide hydrochloride) is added during the foaming process so that it is thoroughly dispersed throughout the foam. The dressings will be available in sizes: 2"x2", 4"x4", 6"x6", 3 1/2"x3", and in 1" diameter.

The following table (Table 1) lists the percentages of different components of the device.

Table 1

Component Name	% by weight
(b) (4) urethane pre-polymer	40.5
USP purified water	58.6
(b) (4) (surfactant)	0.3
(b) (4) (surfactant)	0.6
Plyhexamethylene Biguanide Hydrochloride (PHMB)	5 mg per gm of foam dry weight
Adhesive border	17 mg per gm of dry foam weight

Drug Elution Testing:
Not provided.

Question:

You state that the subject device contains polyurethane foam impregnated with polyhexamethylene biguanide (PHMB) and it is unclear how the drug is bound to the foam. In order to evaluate the safety and efficacy of the subject device, please provide the following information:

- a. A brief description of how the drug is impregnated into the foam.
- b. The nature of bonding involved between the foam and the drug.
- c. The leachability of the drug from the foam. If it leaches out, please provide a comparison of the drug leachability between the subject device and the predicate device, Kerlix Antimicrobial Gauze Dressing.
- d. The experimental details of the elution test including the protocol followed.

Predicate Device:

Kerlix™ Antimicrobial Gauze Dressing (K990530) is a wound dressing consisting of gauze treated with polyhexmethylene biguanidine hydrochloride (PHMB), 0.57%.

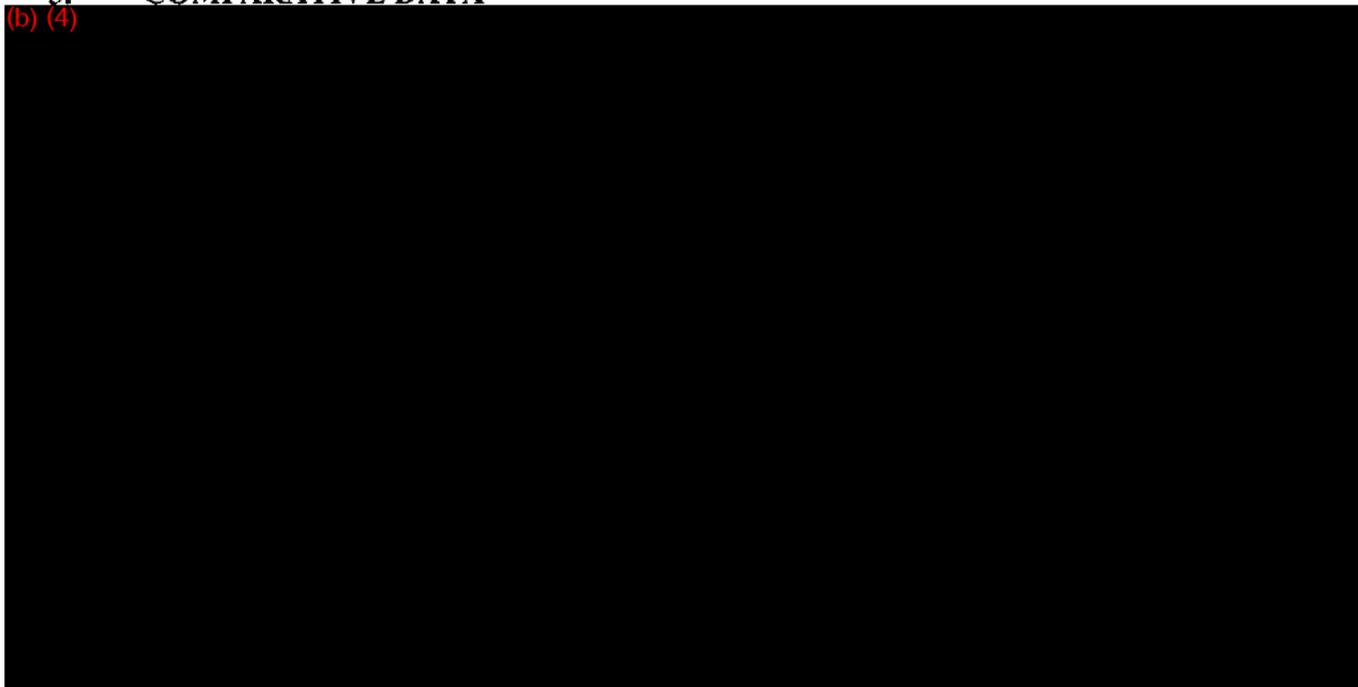
Acetic acid extraction of the device yielded approximately 1350ug/g.

Discussion of Equivalence:

Both subject device and predicate device contain polyhexmethylen biguanide hydrochloride (PHMB) at a concentration of 0.57%.

3. COMPARATIVE DATA

(b) (4)



4. DOES THE PRODUCT CONTAIN DRUGS OR BIOLOGICALS?

Yes, the dressing contains 5 mg/g of foam dry weight (0.5% PHMB by weight).

5. STERILIZATION

Method: EtO

Validation method: ANSI/AAMI/ISO 11135:1994

SAL: 10^{-6}

Pyrogenicity Claims:

None

Packaging:

The subject devices will be packaged in a peel pouches and boxed and are sterilized by EtO

Shelf-life/Expiry Date:

The product label displays product expiration date, but no shelf-life data are provided to support this.

Question:

Your product label indicates that the subject device has expiration date. However, you have not provided shelf-life data to support the product expiration date. Please provide this information.

6. LABELING

The product box label displays: the product name, manufacturer' name and address, sterility condition, drug concentration, lot #, product expiration date.

The package insert contains device description, indications for use, precautions, instructions for use.

7. CLAIMS

The device is an antimicrobial dressing.

8. ADMINISTRATIVE INFORMATION

Truthful and Accurate Statement: See page 008
510(k) Summary: See page 012
Indications for Use: See page 45

9. SUMMARY

Both subject device and predicate device contain 0.5% of the antimicrobial drug, polyhexamethylene biguanide (PHMB). In case of the subject device it is impregnated into polyurethane foam whereas the predicate device is cotton gauze impregnated with PHMB.

Adequate labeling and sterilization information are provided.

Antimicrobial test data reports are not provided.

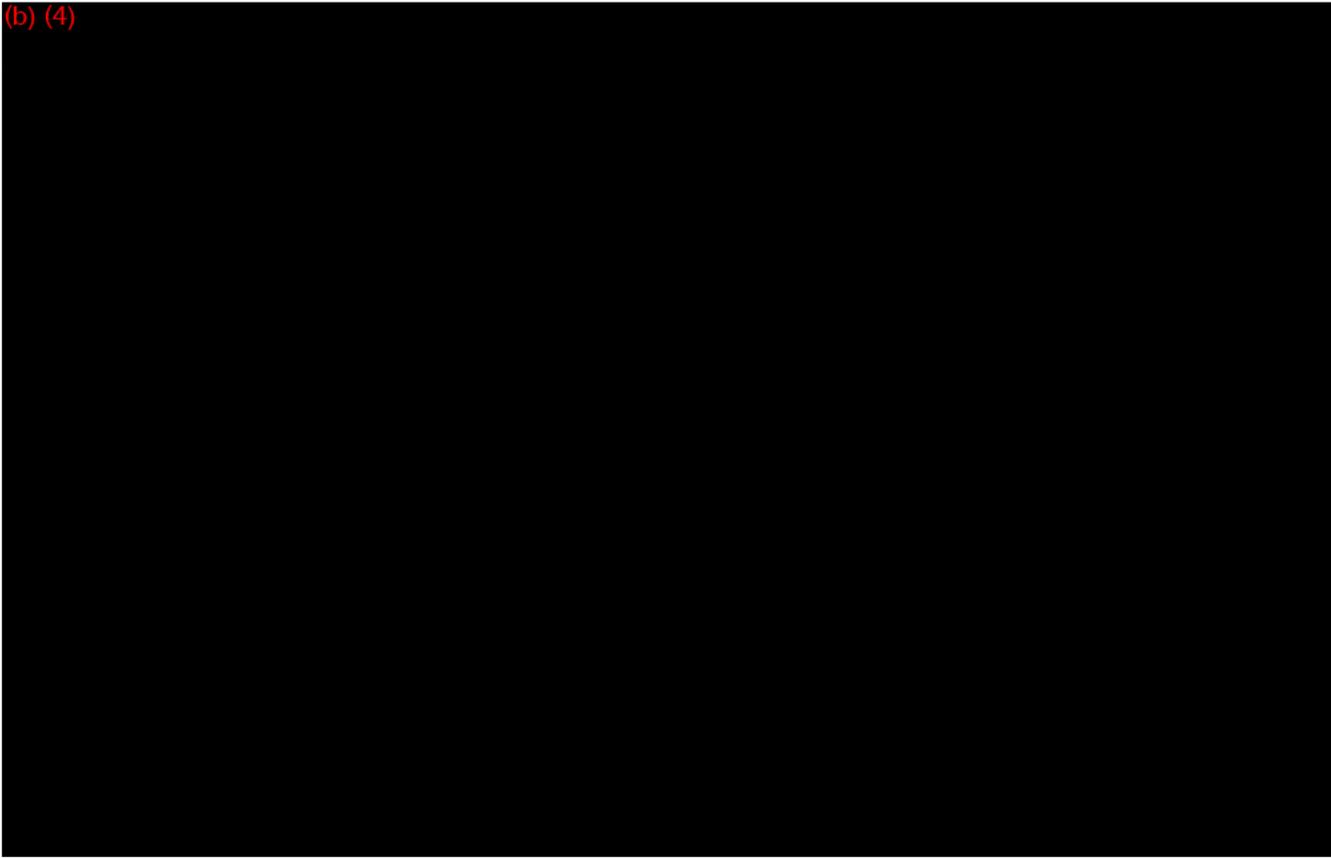
AI requested and the document is put on hold.

10. CONTACT RECORD

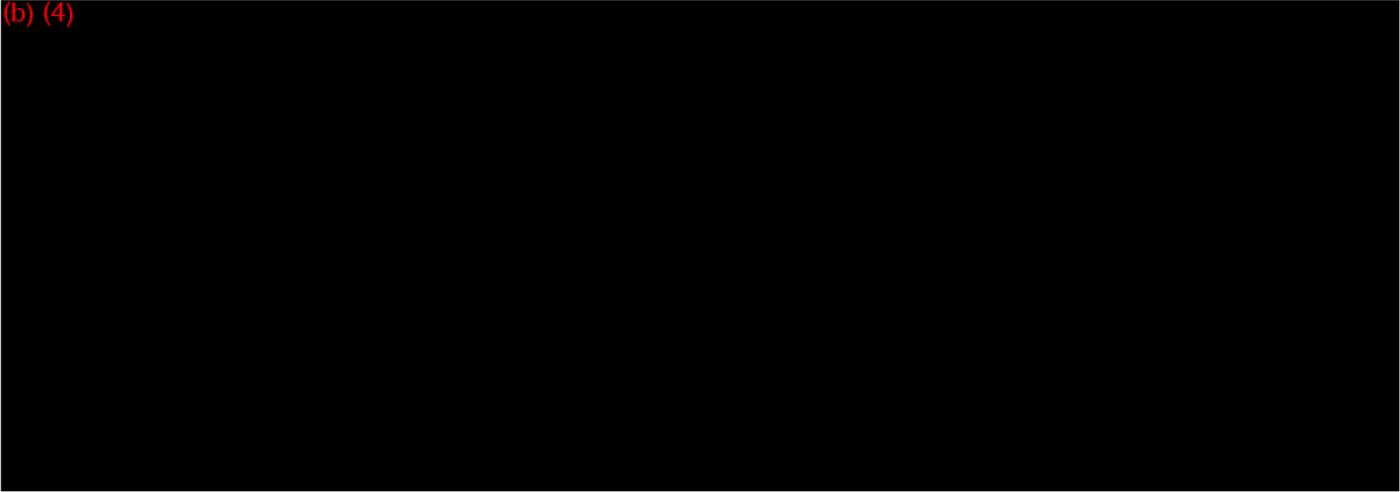
AI letter is sent to sponsor.

DEFICIENCIES

(b) (4)



(b) (4)



Sam Arepalli, Ph.D.
FDA/CDRH/ODE/DGRND/PRSB

6/6/07
Date

Arepalli, Sambasiva

From: Provost, Miriam
Sent: Friday, May 18, 2007 3:33 PM
To: Krause, David; Arepalli, Sambasiva; Rhodes, Stephen
Cc: Melkerson, Mark N.
Subject: RE: NME Issues

Hi David,

(b) [Redacted]

Miriam

From: Krause, David
Sent: Friday, May 18, 2007 3:15 PM
To: Provost, Miriam; Arepalli, Sambasiva; Rhodes, Stephen
Cc: Melkerson, Mark N.
Subject: RE: NME Issues

(b) (4) [Redacted]

David

From: Provost, Miriam
Sent: Friday, May 18, 2007 1:04 PM
To: Krause, David; Arepalli, Sambasiva; Rhodes, Stephen
Cc: Melkerson, Mark N.
Subject: RE: NME Issues

(b) [Redacted]

Miriam

From: Krause, David
Sent: Friday, May 18, 2007 12:51 PM
To: Provost, Miriam; Arepalli, Sambasiva; Rhodes, Stephen
Cc: Melkerson, Mark N.
Subject: RE: NME Issues

(b) (4) [Redacted]

David

From: Provost, Miriam
Sent: Friday, May 18, 2007 12:26 PM

To: Arepalli, Sambasiva; Rhodes, Stephen
Cc: Krause, David; Melkerson, Mark N.
Subject: RE: NME Issues

Sam,

(b) (4)

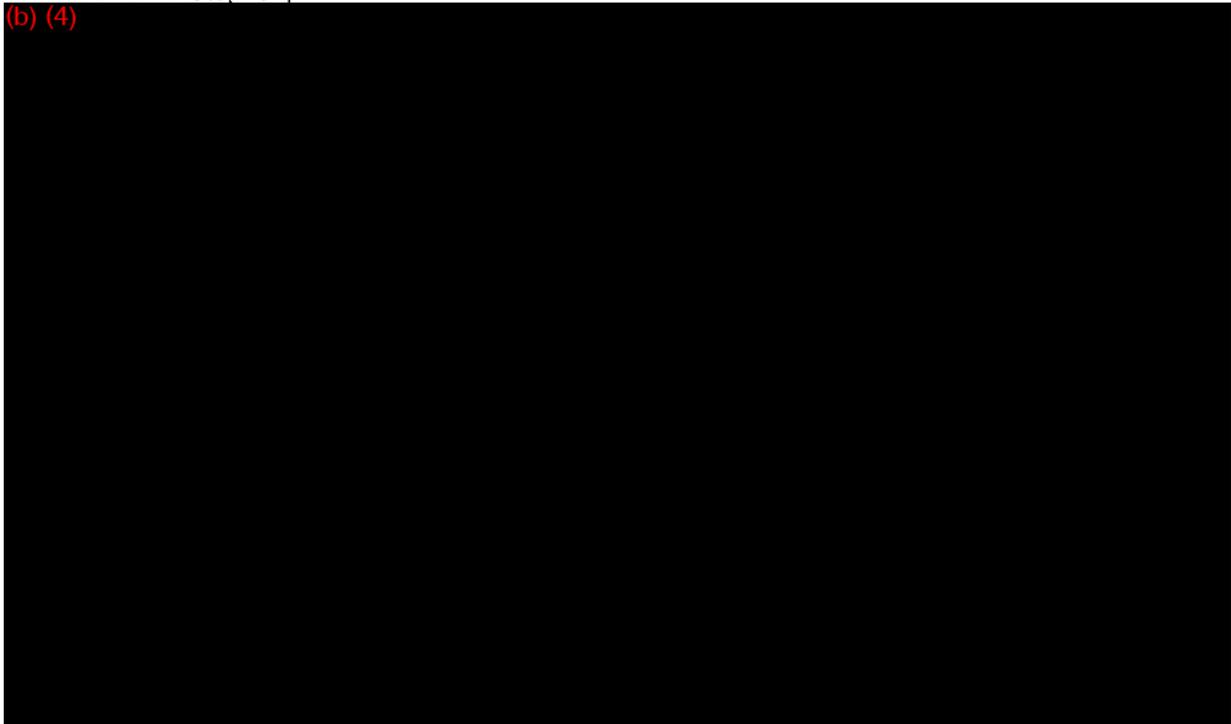


Miriam C. Provost, Ph.D.
Deputy Director
Office of Device Evaluation
CDRH/FDA
(240) 276-3983

From: Arepalli, Sambasiva
Sent: Friday, May 18, 2007 10:19 AM
To: Provost, Miriam; Rhodes, Stephen
Cc: Krause, David; Melkerson, Mark N.; Arepalli, Sambasiva
Subject: NME Issues

Miriam and Stephen,

(b) (4)



Sam

Sam Arepalli, Ph.D.
Reviewer
Plastic & Reconstructive Surgery Devices Branch
Division of General, Restorative and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health
FDA/DHHS
(240) 276 3626

510 (K) MEMORANDUM

TO: K011941
FROM: ODE/DGRND/Plastic and Reconstructive Surgery Devices Branch
DATE: August 8, 2001
SUBJ: *Device Name: Excilon^{AM} Antimicrobial Sponge Model #7088*
Sponsor: The Kendall Co.
Contact Name and phone number: Michael Spears
(508) 261-8155

Recommendation: SE
Procode: NAD
Class: I
Device Category: Dressing
CFR Section: 878.4020

REVIEW:

1. Is the product a device? Combination Product? Why?

This product is a device because it is intended to affect the structure of the body and does not achieve any of its primary intended purposes through chemical action within the body. This dressing is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

It is a combination product since it is coated with 1% Cosmocil® CQ with its active ingredient being Polyhexanethylene Biguanide Hydrochloride (PHMB).

2. Indication and/or Intended Use Statement

Subject Device

Excilon® A.M.D. Antimicrobial Sponges are intended for use as primary dressings for IV sites, Tracheostomy tube sites, chest tube sites, catheter sites and drain sites. The antimicrobial activity of the PHMB in Excilon® A.M.D. helps to resist bacterial colonization of the dressing and inhibit bacterial penetration through the dressing. The barrier function of the dressing may help reduce infections in partial and full thickness wounds.

Predicate Device(s)

Kendall Kerlix Antimicrobial Gauze (K990530) is intended for use as a primary dressing for

K011941
Excilon AMD Antimicrobial Sponge Model
August 8, 2001

exuding wounds, first and second degree burns, and surgical wounds, to secure and prevent movement of a primary dressing, and as a wound packing.

The [REDACTED] (silver coated contact layer dressing (k 992221) is an effective barrier to bacterial and fungal penetration. The barrier function of the dressing may help reduce infections in partial and full thickness wounds including decubitus ulcers, first-and second-degree burns, donor sites and surgical wounds. It may be used over debrided and grafted partial thickness wounds.

Discussion of equivalency

Technological Characteristics (Design, Materials, Sizes, etc.)

Subject Device

Materials

Sizes

(b) (4)

Predicate Devices

Kendall Kerlix Antimicrobial Gauze (K990530) 6"x 6.75" (15cm x17 cm) Stretched
USP Gauze treated with PHMB

The [REDACTED] (silver coated contact layer dressing - 4"x 4" (10 cm x 10 cm)
3-ply gauze dressing with an absorbent rayon/polyester core
with an upper and lower layer of silver coated high density polyethylene mesh
Non-woven mesh

Discussion of equivalency

There are no new technological characteristics. The subject device and Kendall Kerlix Antimicrobial Gauze both contain the same amounts of PHMB (b) (4)

Both (b) (4) Primary Antimicrobial Dressing and Excilon A.M.D. utilize non-woven materials with antimicrobial coatings with [REDACTED] utilizing a silver active agent.

3. Comparative Performance Data (in vitro, animal and/or clinical)

Effectiveness Data

Subject Device

In-vitro testing has demonstrated that Excilon AMD Drain Sponges resist microbial penetration and growth of a broad spectrum of microorganisms. The squares of Excilon AMD Drain Sponges, untreated sterile Excilon Drain Sponges and positive controls were

K011941
Excilon AMD Antimicrobial Sponge Model
August 8, 2001

plate was observed for microbial growth following incubation. The results indicated that Excilon AMD Drain Sponges were effective in preventing the growth of the test organisms. placed on agar plates. This was done for both (b) (3) (B) [REDACTED]
(b) Each disc was inoculated with (b) (4) [REDACTED]
[REDACTED]

Predicate Device(s)

Laboratory testing has shown that each antiseptic agent has a broad spectrum of antimicrobial activity.

Discussion of Equivalency

All three dressings have help resist bacterial colonization of the dressing and bacterial penetration through the dressing. This barrier function may help reduce infections in partial and full thickness wounds

5. Sterilization

Method - Steam
Validation - AAMI Overkill Method of Cycle Development
Dose -
Sterility Assurance Level - 1×10^{-6}
Packaging - Paper -to-paper pouch
Pyrogenicity claims - No label claim is made that the device is "non-pyrogenic"

6. Labeling

(OTC and/or Prescription)- Prescription
Package Insert (Section 8)
Carton/Pouch Labels (Section 1, page 1)

7. Has sponsor provided all administrative requirements?

- Truthful and Accurate Statement (Page 10)
- 510(k) Summary or Statement (Exhibit 12)
- Indication for Use Page (Exhibit 12)

8. Summary

This dressing is equivalent to the predicate kerlix dressing in that they both contain the same amount of antimicrobial, Polyhexamethylene Biguanide Hydrochloride (PHMB). The Excilon wound dressing, excluding the antimicrobial agent, is the same dressing which the Kendall Healthcare Company had been selling since 1987. Both the subject dressing and the Acticoat dressing utilize non-woven materials. Therefore, I would find this device to be substantially equivalent.

K011941
Excilon AMD Antimicrobial Sponge Model
August 8, 2001

9. Contact History/Requests for More Information:
None

Laurie Bernato 8/9/01
Name D. Laurie Bernato Date
Plastic and Reconstructive Surgery Devices Branch

510(k) Number (if known): K011941

Device Name: Excilon A.M.D. Antimicrobial Sponge

Indications For Use:

Primary dressing for IV sites, tracheostomy tube sites, chest tube sites, catheter and drain sites.

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

Concurrence of CDPM, Office of Device Evaluation (ODE)

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

510(k) Number K011941

Prescription Use X
(Per 21 CFR 801.109)

OR

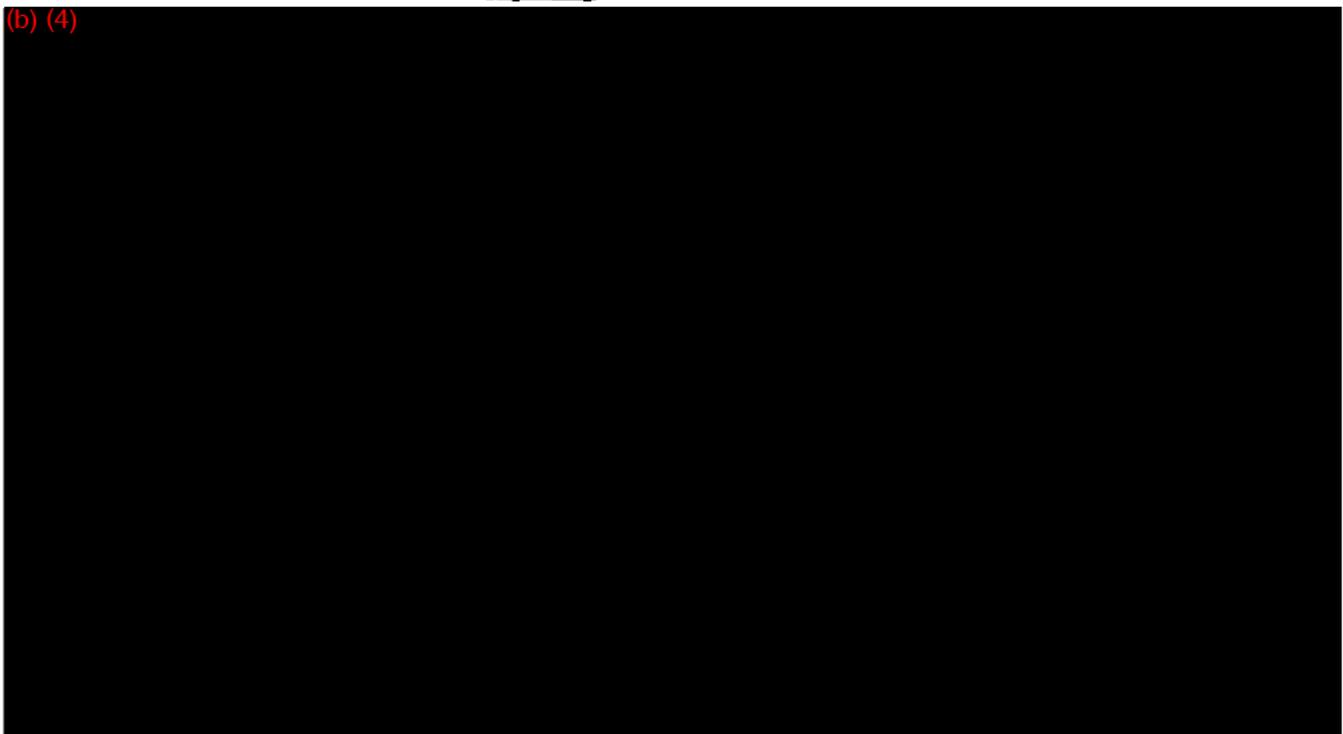
Over-The-Counter Use

(Optional Format 1-2-96)

3

1.0 Physical and Chemical Properties

(b) (4)



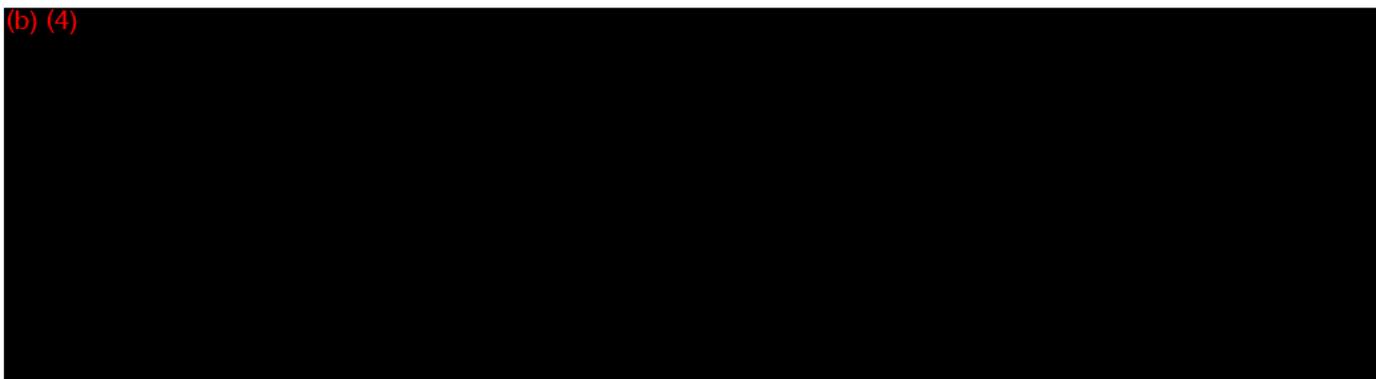
1.1 Solubility

(b) (4)



1.2 Preparation and Stability of Solutions

(b) (4)



1.3 Compatibility

(b) (4)



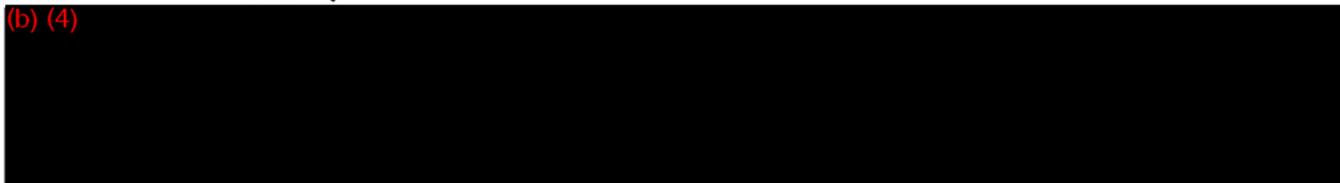
1.4 Effect of pH

(b) (4)



1.5 Surface Activity

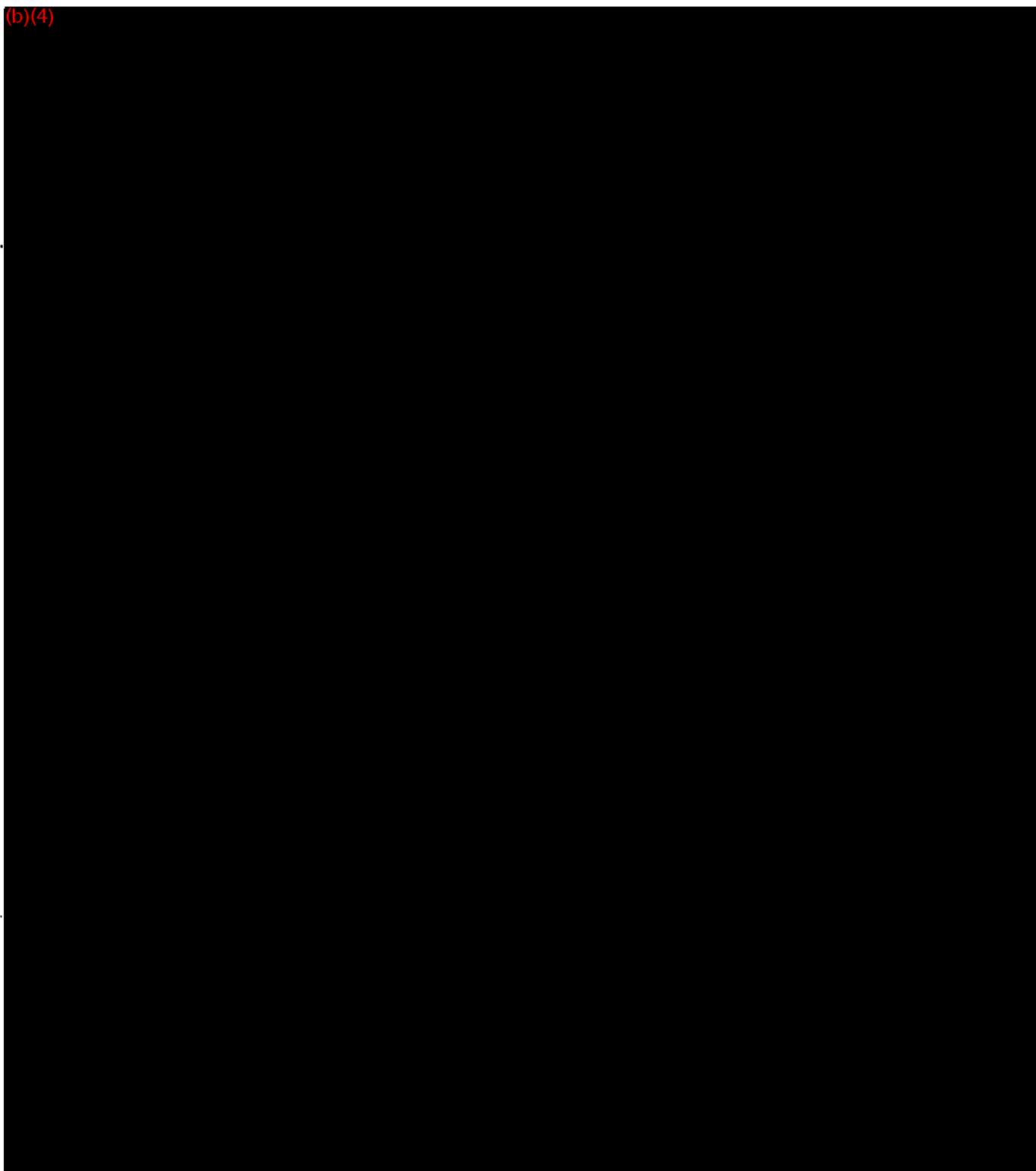
(b) (4)



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2.0 Bacteriostatic Activity

(b)(4)

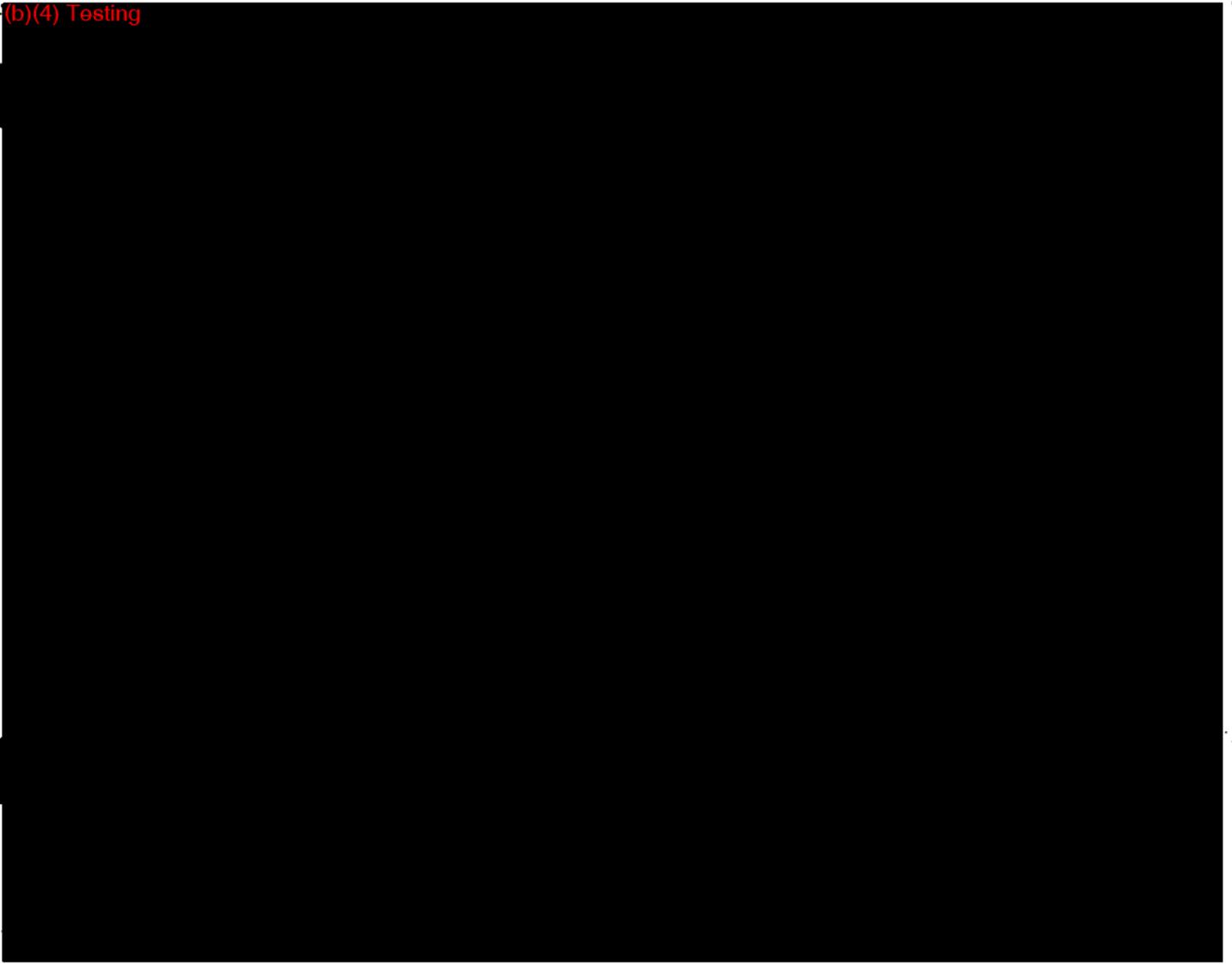


ES

(b)(4)



(b)(4) Testing



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(b)(4) Testing

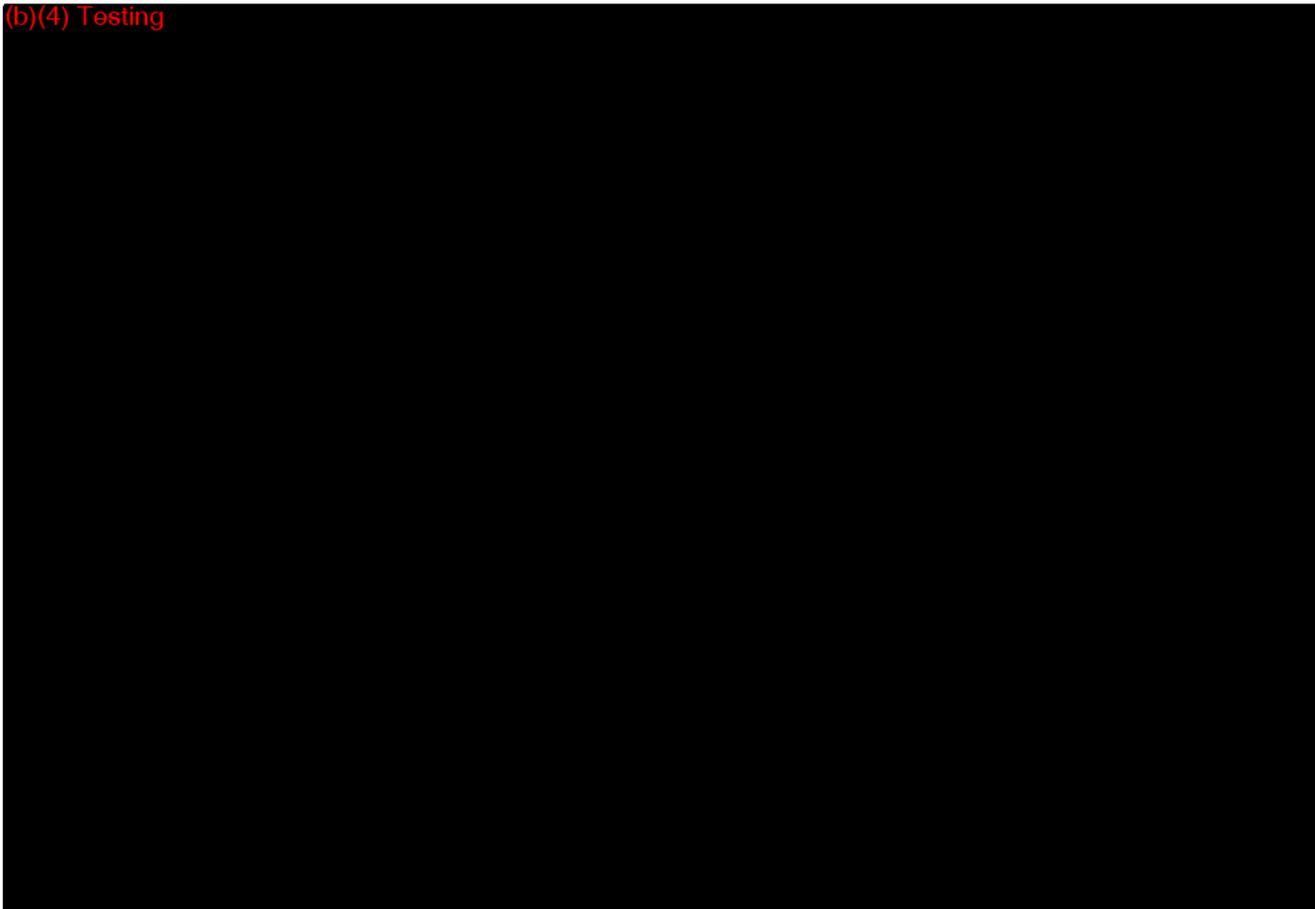


TABLE 1

COMPOSITIONS OF THE COSMETIC CREAMS USED

(b) (4)

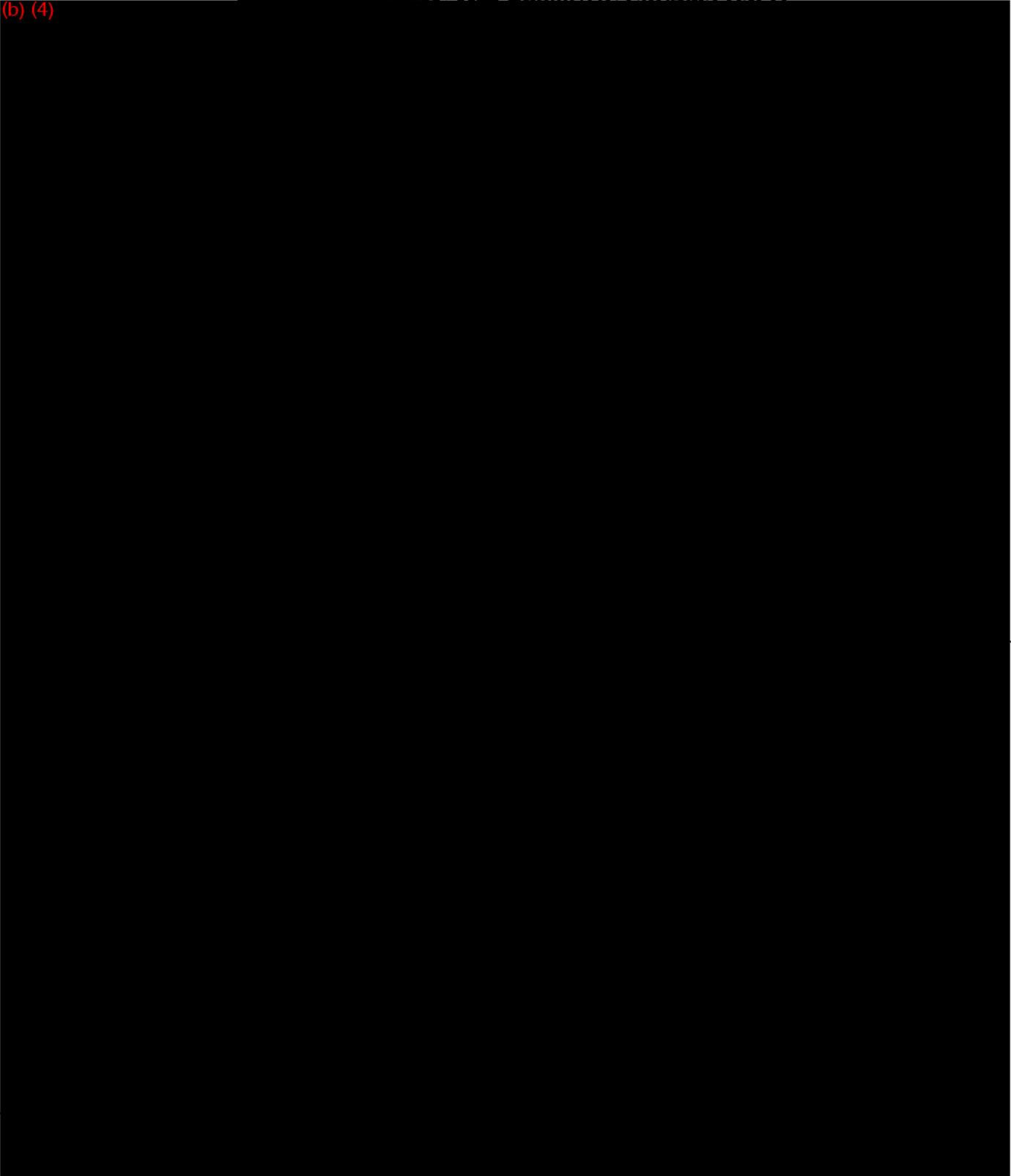
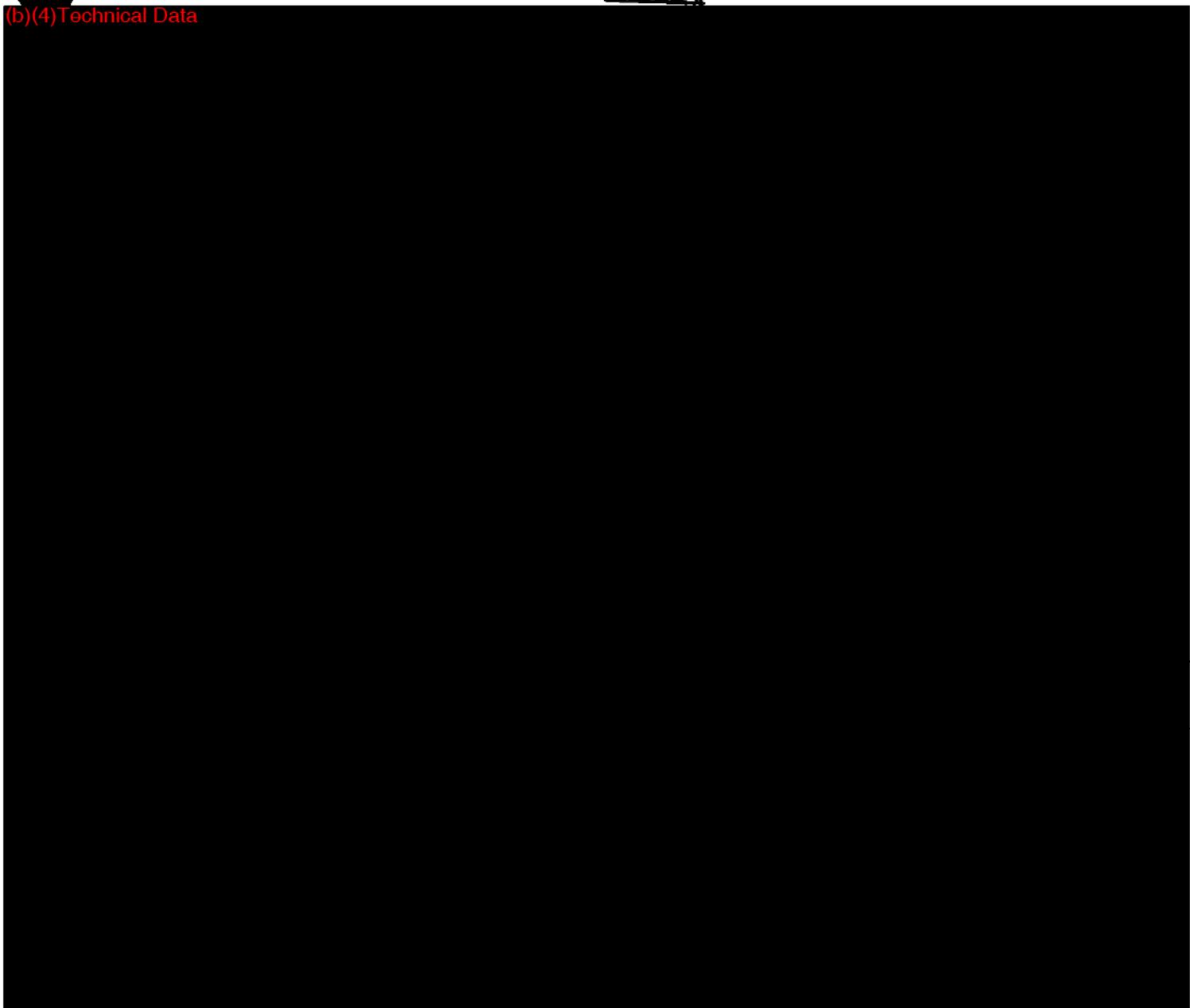


TABLE 2

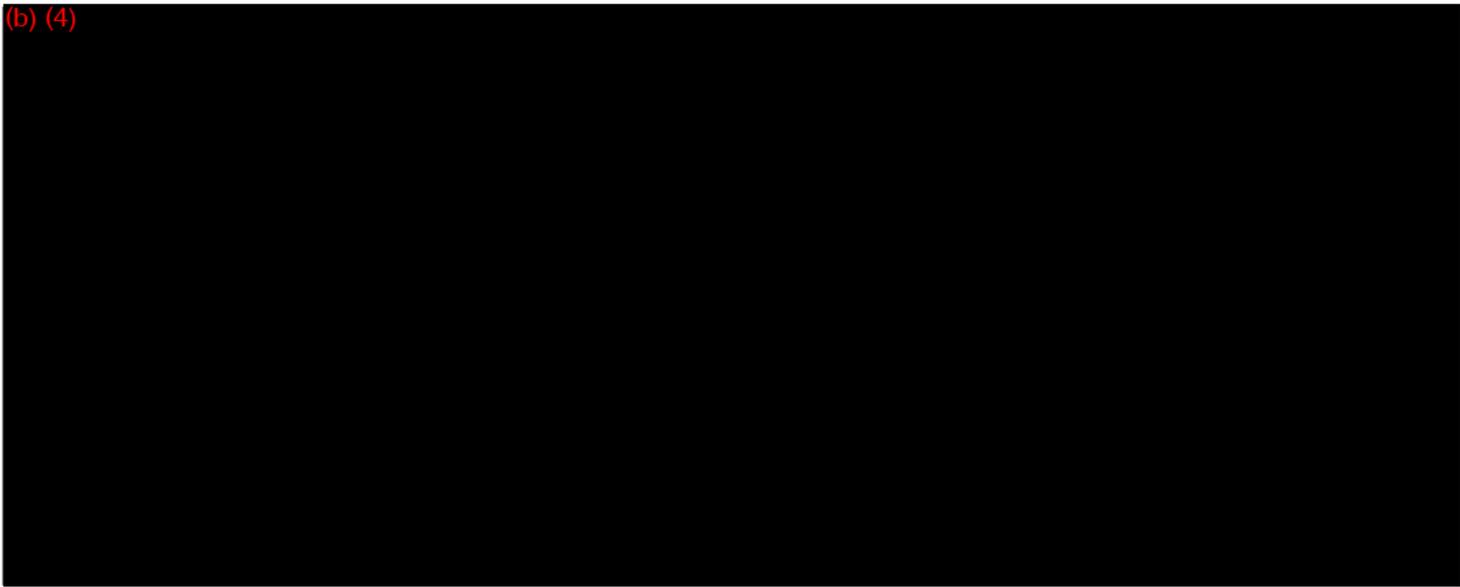
(b)(4) Technical Data



51

120

(b) (4)



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MEMO TO THE RECORD
510(K) REVIEW
K990530/S001

DATE: 1/28/00
OFFICE: HFZ-410
DIVISION: DGRD/PRSB
FROM: Biologist
DEVICE NAME: Kerlix ~~AD~~ Antimicrobial Gauze Dressing
COMPANY NAME: Kendall Company

NARRATIVE DEVICE DESCRIPTION

INTENDED USE: The device is intended for use as a primary dressing for exuding wounds, first and second degree burns, and surgical wounds, to secure and prevent movement of a primary dressing, and as a wound packing. These indications are consistent with other wound dressing premarket notifications.

DEVICE DESCRIPTION:

Is the device:

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

Device(s) to which equivalence is claimed and its manufacturer(s):

- (1) K895993: Biopatch, Johnson & Johnson (device contains 4% chlorhexidine gluconate)
- (2) K973657: Arglaes, Maersk Medical Ltd.

SUMMARY

The device is a sterile, single use, wound dressing consisting of gauze treated with Polyhexamethylene Biguanide Hydrochloride (PHMB) (b) (4). The dressing will be available in both patch and roll form. (b) (4)

[REDACTED]

[REDACTED] (b) (4)

MATERIALS:

See attached reviews (4/23/99 and 1/27/00) for summaries of biocompatibility and antimicrobial testing conducted.

STERILITY:

(b) (4)

PACKAGING: Tyvek/Poly pouch or Tyvek/Styrene tray

LABELING:

[REDACTED] (b) (4)

This

(b) (4)

[REDACTED]

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

RECOMMENDATION: Substantially equivalent to 79 NAD, Occlusive wound and burn dressing

CLASSIFICATION: Class I

P. L. Hudson

Peter L. Hudson, Ph.D.

Reviewer

Division of General and Restorative Devices
Plastic and Reconstructive Surgery Branch

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MEMO TO THE RECORD
K990530/S001

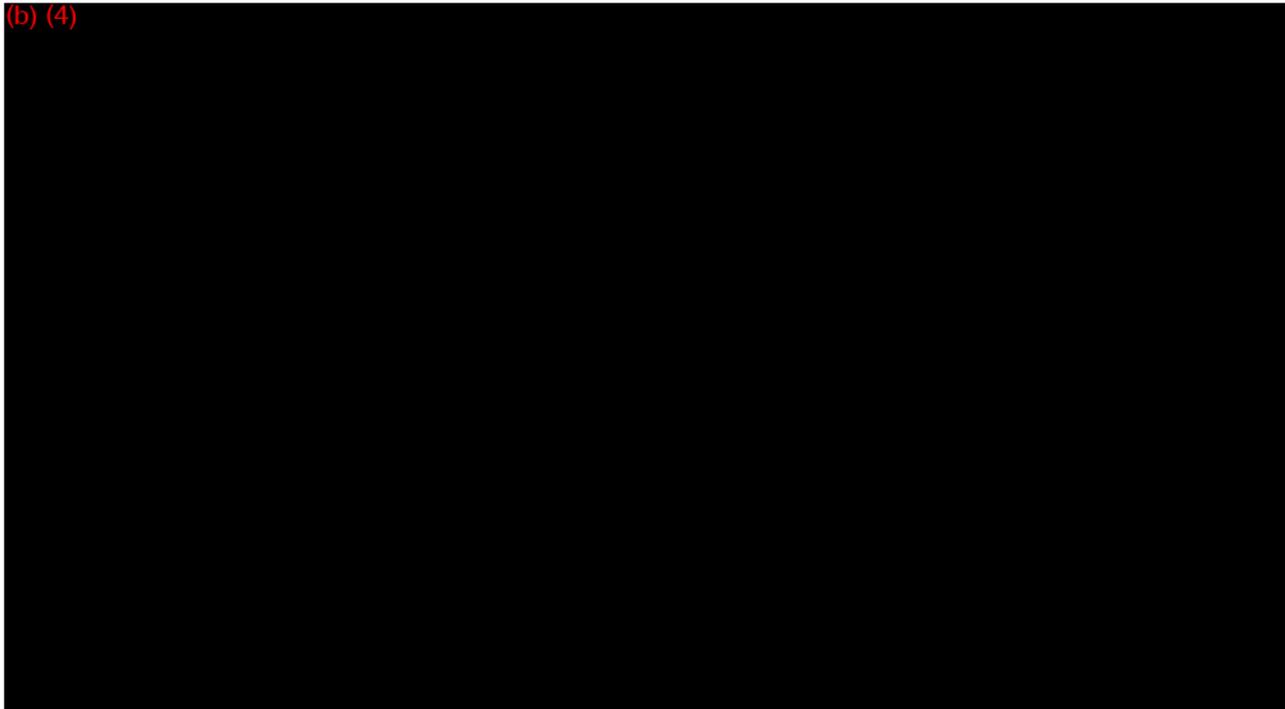
DATE: 1/27/00
OFFICE: HFZ-410
DIVISION: DGRD/PRSB
FROM: Biologist
RE: supplemental information submitted during RFD for KerlixTM MD
Antimicrobial Gauze Dressing
APPLICANT: The Kendall Company
CONTACT: Mr. Frank Fucile
PHONE: 508-261-8532

Recommendation: The device is found to be substantially equivalent.

Review

A meeting between the sponsor of the product and FDA was held on October 21, 1999 to discuss which Center should be designated to review the product. As a result of the meeting the product was determined to be a device. The information presented by the sponsor is to be used as the additional information requested of the sponsor to demonstrate that the drug contained in the dressing is biocompatible. The following review is of the new information submitted. For a summary of the preclinical and clinical testing conducted and reviewed previously, see my review of April 23, 1999. The following questions and answers are from the consult review provided by David Bostwick of CDER.

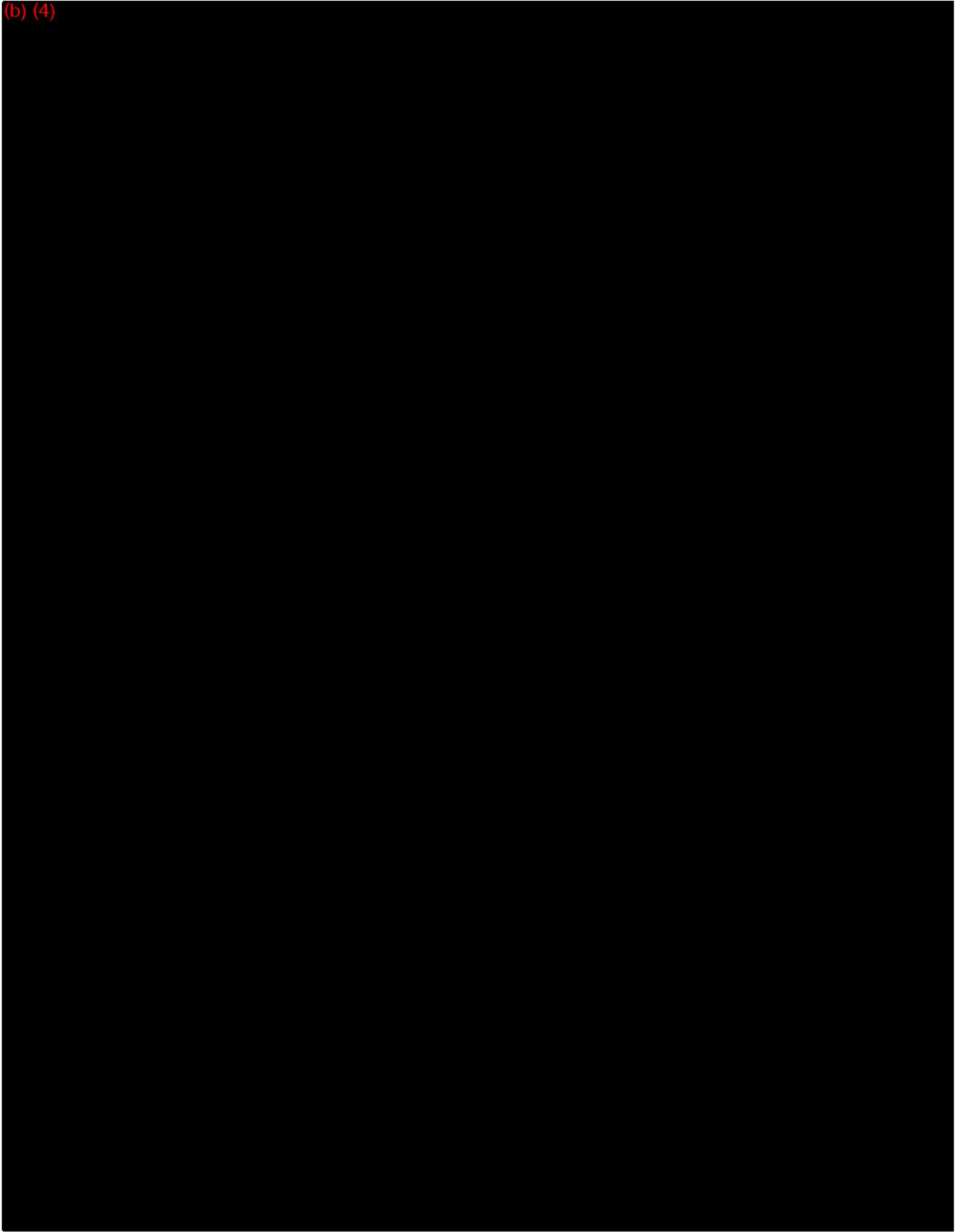
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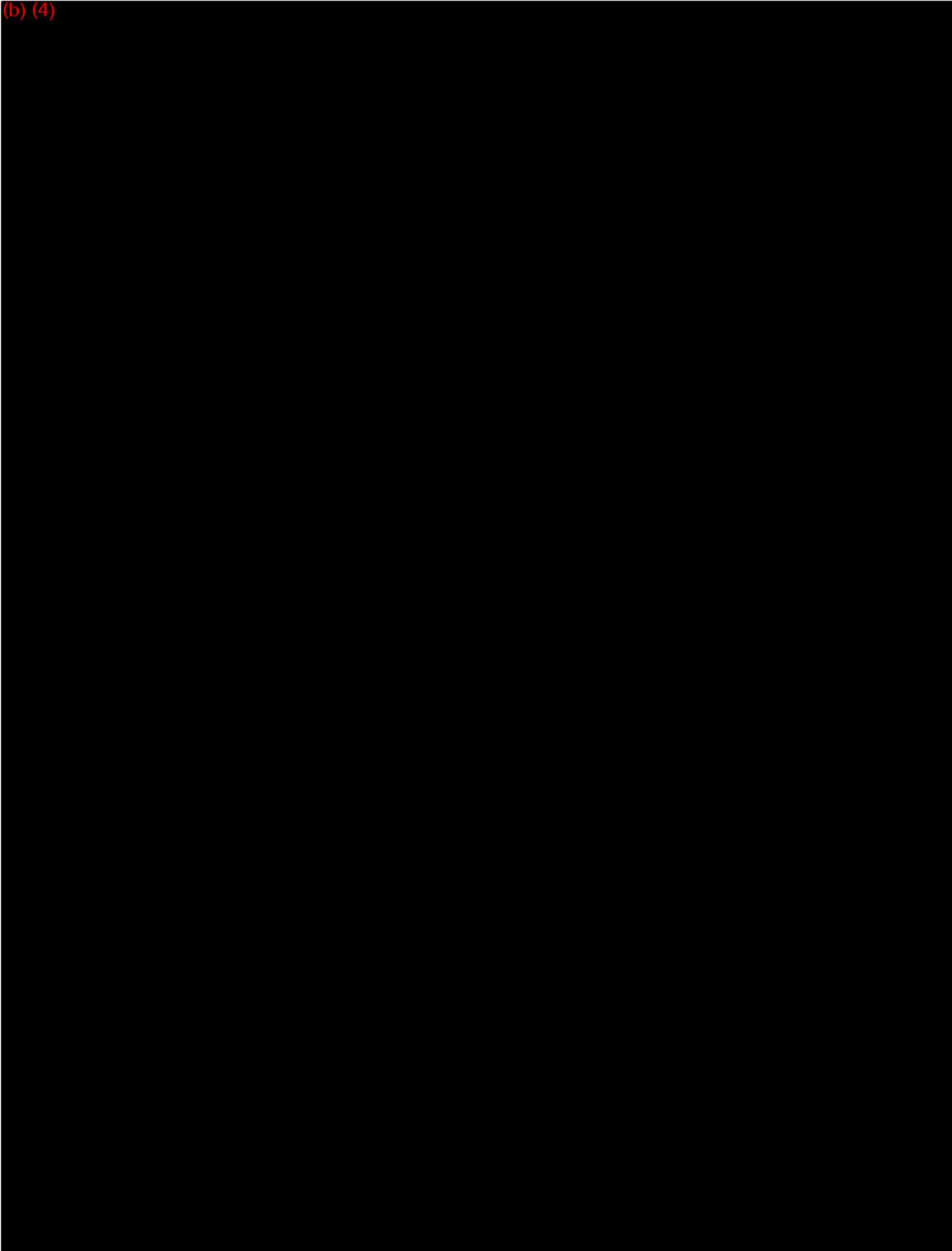
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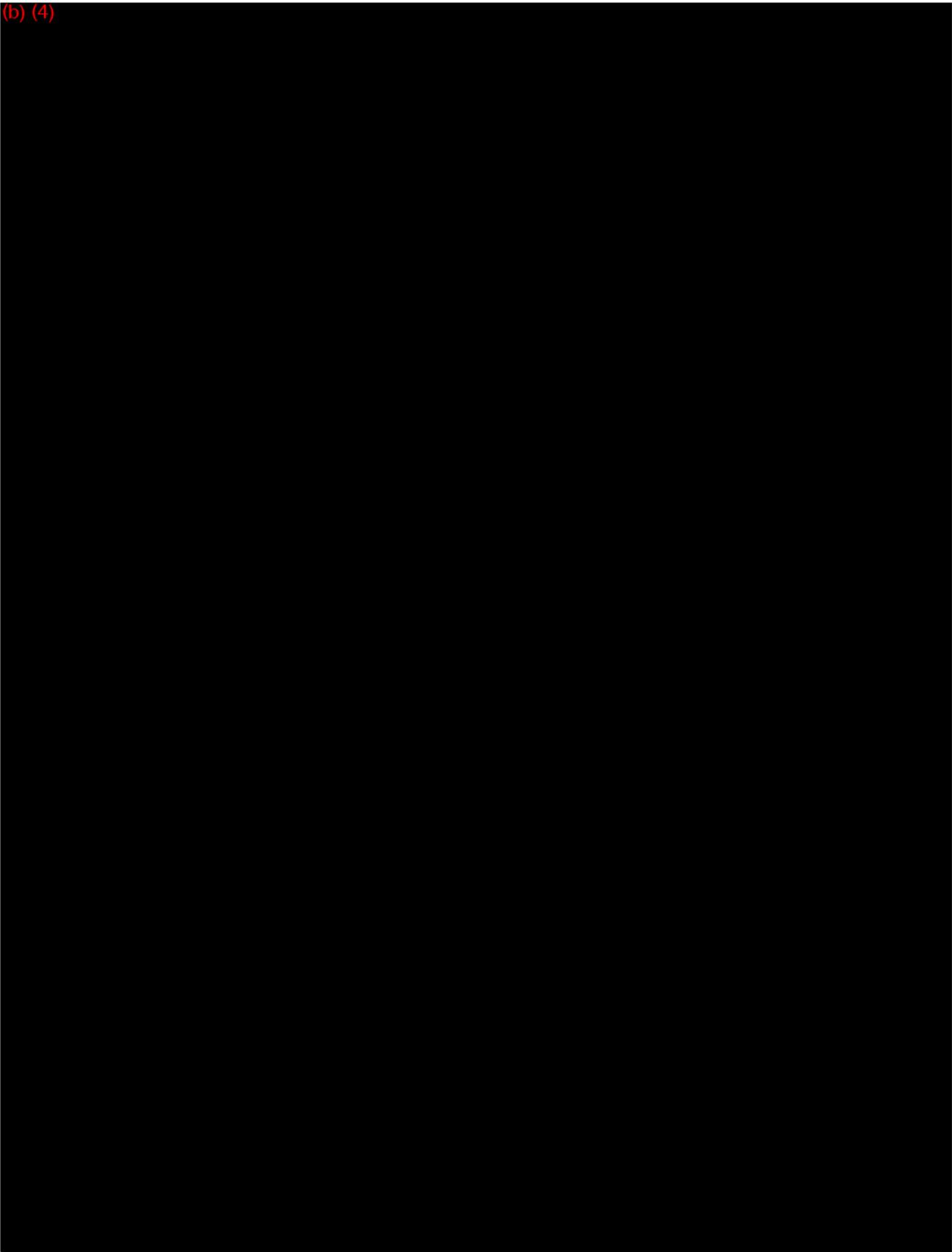
(b) (4)



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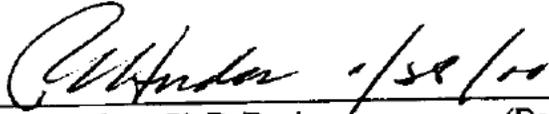
(b) (4)



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Labeling

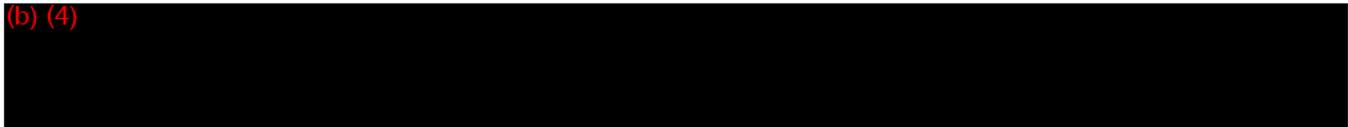
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Peter L. Hudson, Ph.D./Reviewer (Date)

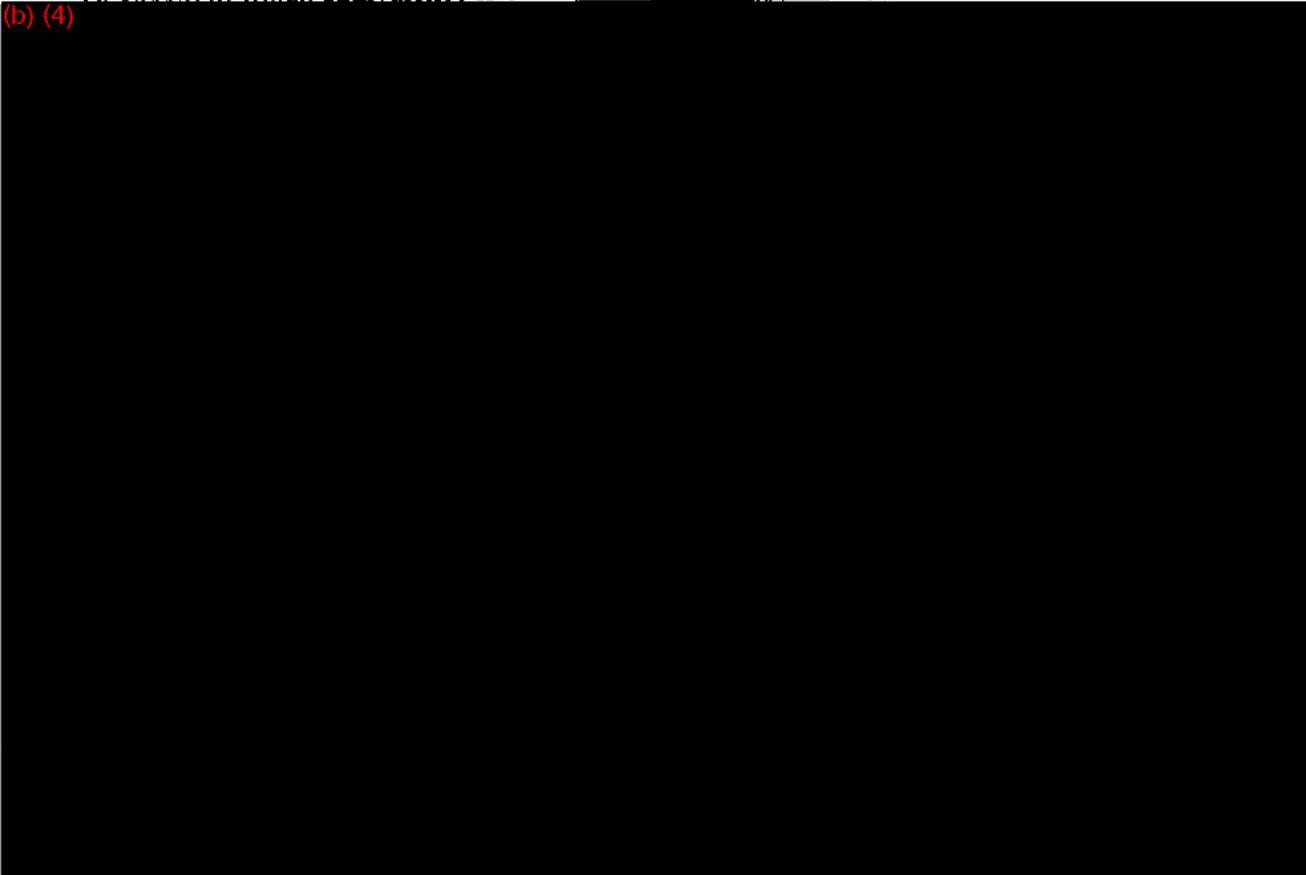
Division of General and Restorative Devices
Plastic and Reconstructive Surgery Branch

(b) (4)

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Device(s) to which equivalence is claimed and its manufacturer(s):

(b) (4)

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Biocompatibility testing conducted:

(b) (4)

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(b) (4)

(b) (4)

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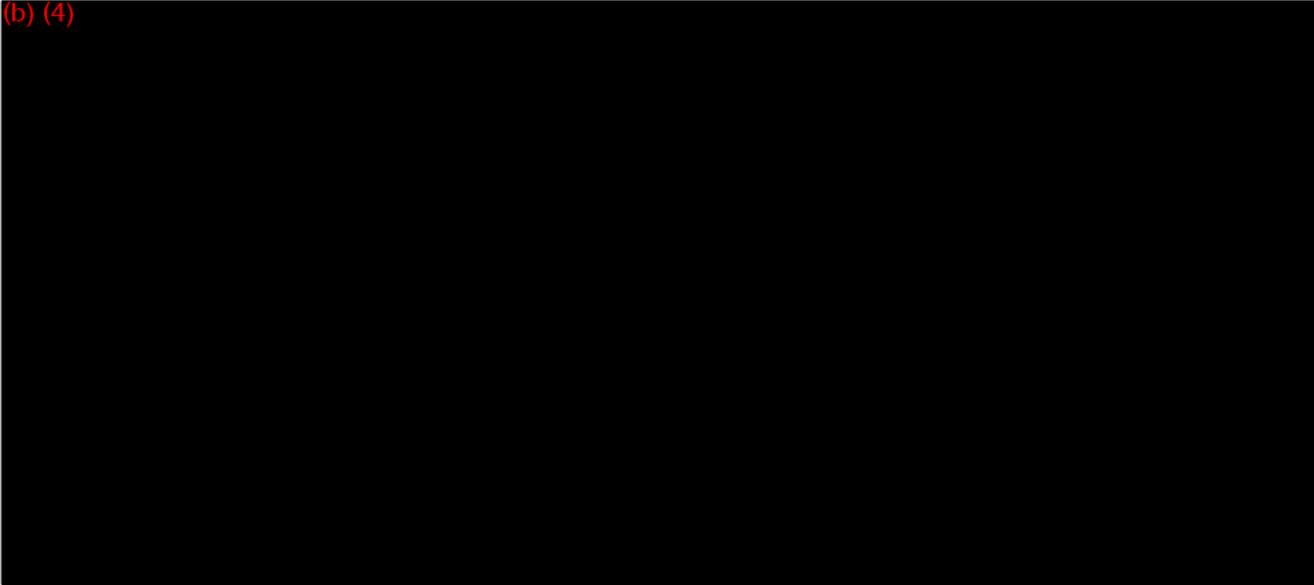
Consult

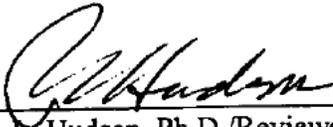
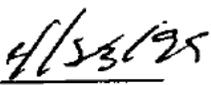
(b) (4)

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20

(b) (4)



 
Peter L. Hudson, Ph.D./Reviewer (Date)
Division of General and Restorative Devices
Plastic and Reconstructive Surgery Branch

21

K990530

INDICATIONS FOR USE STATEMENT

510K Number: K990530

Device Name: Kendall **KERLIX™** Antimicrobial Gauze

Indications for Use:

KERLIX Antimicrobial Gauze is intended for use as a primary dressing for exuding wounds, first and second degree burns, and surgical wounds, to secure and prevent movement of a primary dressing, and as a wound packing

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(per 21 CFR 801.109)

OR Over-the-Counter Use _____



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K-990530

3

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

September 11, 2007

TYCO HEALTHCARE GROUP, LP
15 HAMPSHIRE ST.
MANSFIELD, MA 02048
ATTN: JAMES WALSH

510(k) Number: K071371
Product: COPA AMD
ANTIMICROBIAL
WOUND DRESSING

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1567.html>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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

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

Sincerely yours,

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

K071371/SI

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

September 7, 2007

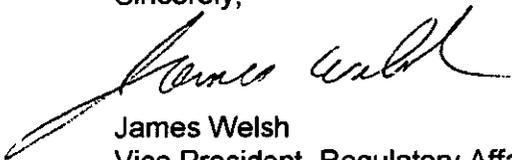
RE: 510(k) # K071371 Premarket Notification for COPA AMD Antimicrobial Foam Wound Dressing

Dear Dr. Arepalli:

This letter is in response to the deficiency letter dated June 11, 2007, as clarified in our phone conversation of August 29th, 2007. For ease of reading, I have restated each question followed by the response. For some questions, revised pages are included. For other questions, new information is provided in the appendices to this letter, and the numbering of these appendices begins at #6, so as not to duplicate the numbering in the original submission.

Please contact the undersigned at (508) 261-8532 should you have any additional questions.

Sincerely,



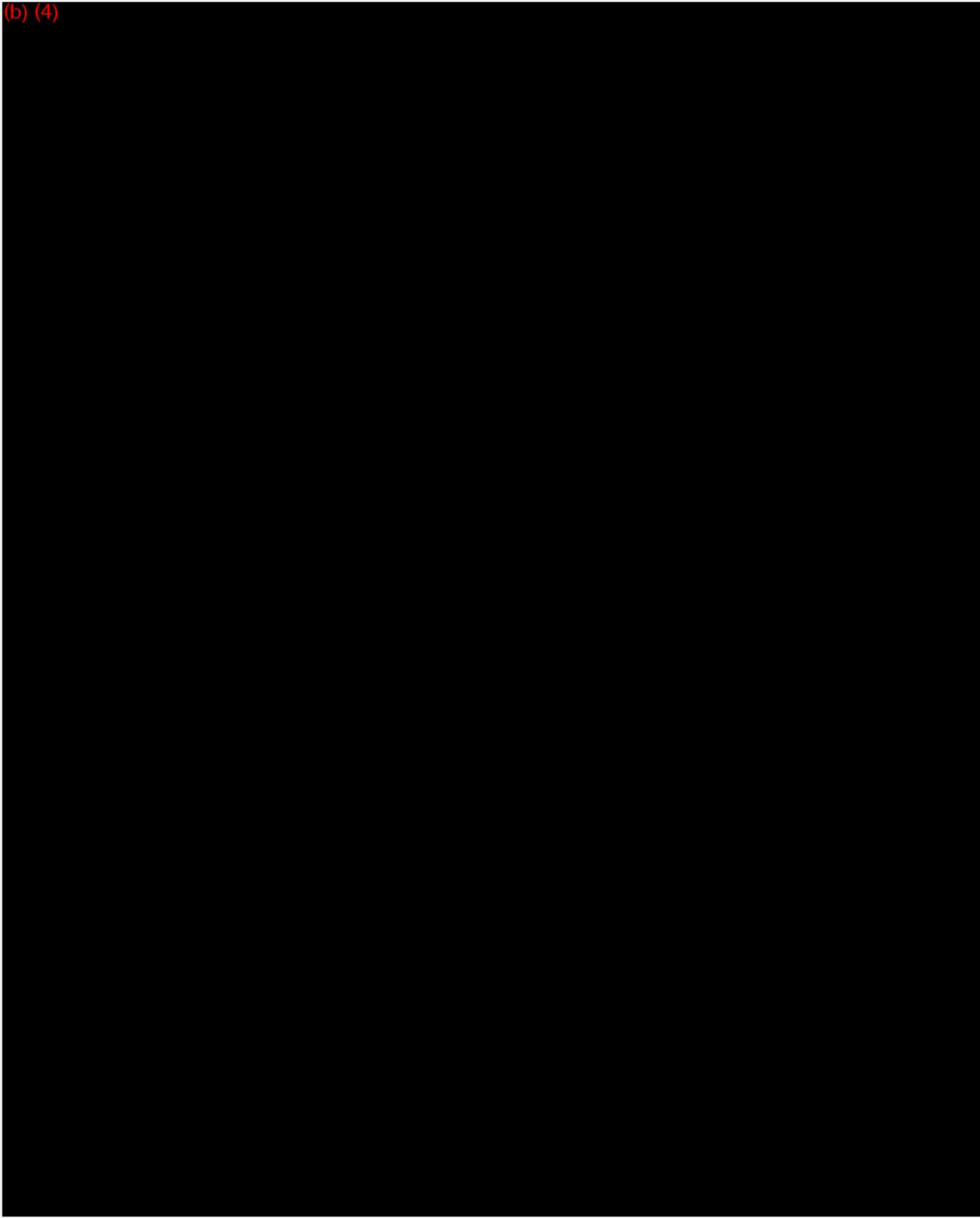
James Welsh
Vice President, Regulatory Affairs
Tyco Healthcare/Kendall

Enclosure

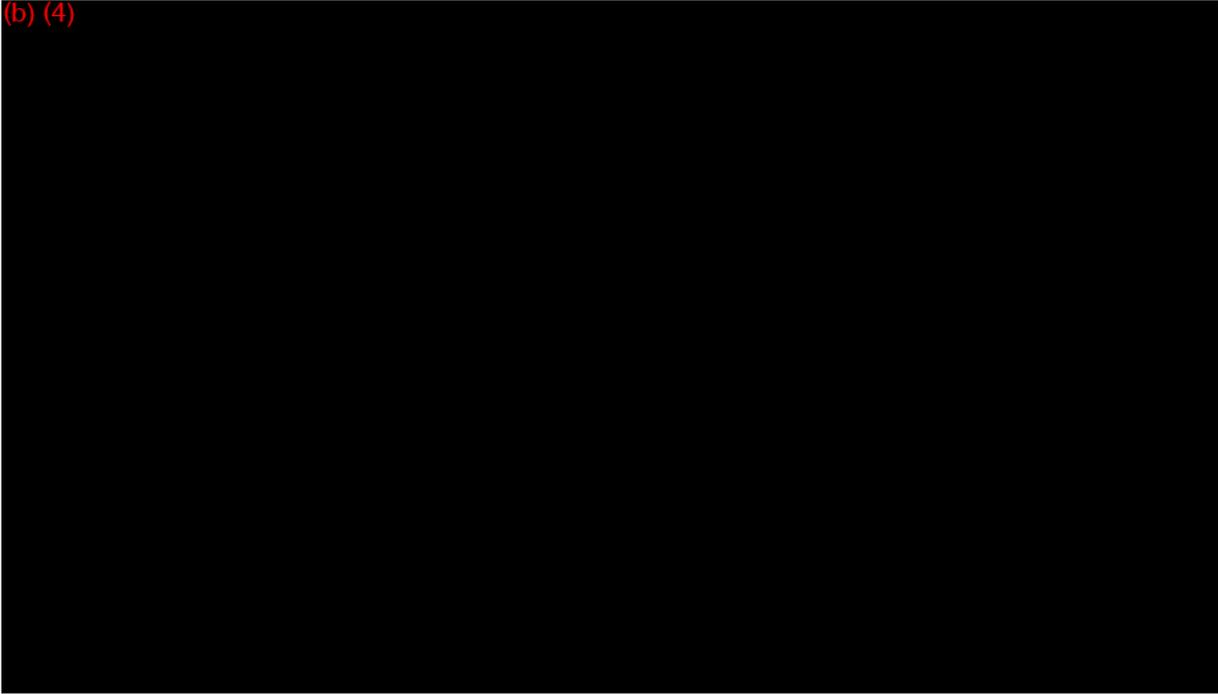
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(b) (4)



(b) (4)



Replacement pages associated with question # 1

510(k) Premarket Notification
COPA AMD Antimicrobial Wound Dressing

Section A – General Device Summary (Continued)

Sponsor Information (continued)

Contact Information:

James Welsh
VP, Regulatory Affairs
Kendall
a Division of Tyco Healthcare Group LP
15 Hampshire Street
Mansfield, MA 02048
Phone: (508) 261-8532
Fax: (508) 261-8461

Purpose of Submission

The purpose of this submission is to obtain FDA clearance for a polyurethane foam wound dressing which contains PHMB (Polyhexamethylene Biguanide Hydrochloride) to inhibit microbial growth within the dressing. This notification includes the appropriate information to demonstrate substantial equivalence of the proposed device to the legally marketed predicate device. A 510(k) summary is provided in **Section B** of this notification.

Indications / Intended Use

COPA AMD dressings are indicated for use in management of post-surgical incisions, pressure sores, venous stasis ulcers, diabetic ulcers, donor sites, abrasions, lacerations, 1st and 2nd degree burns, dermatologic disorders, other wounds inflicted by trauma and, as a secondary dressing or cover dressing for packed wounds.

The Indications for Use Statement is provided in **Appendix 1** of this notification.

Performance Standards

No applicable performance standards pertaining to this device have been issued under section 514 of the Food, Drug and Cosmetic Act.

Predicate Devices

Curafoam Polyurethane Foam Dressings, K946269, cleared 1/12/95
Kerlix AMD Antimicrobial Gauze Dressing K990530, cleared 1/31/00
Excilon AMD Antimicrobial Sponge K011941, cleared 8/22/01

510(k) Premarket Notification
COPA AMD Antimicrobial Wound DressingK071371
page 1 of 2**Section B – 510(K) Summary****Date Summary
Was Prepared:**

May 11, 2007

**Submitter's
Information:**Kendall
a Division of Tyco Healthcare Group LP
15 Hampshire Street
Mansfield, MA 02048
Phone: 508-261-8000
Fax: 508-261-6644**Contact:**James Welsh
VP, Regulatory Affairs
Kendall
a Division of Tyco Healthcare Group LP
Telephone: 508-261-8532
Fax: 508-261-8461**Device Trade****Name:** COPA AMD Antimicrobial Wound Dressing**Device Common****Name:** Wound Dressing, Antimicrobial**Classification Panel:** General and Plastic Surgery**Legally Marketed Devices To Which Substantial Equivalence Is Claimed:**

The COPA AMD antimicrobial wound dressing is substantially equivalent to the existing COPA (Curafoam) polyurethane foam wound dressings in intended use, materials, physical characteristics, and performance characteristics. The modification attributed to the predicate device is the addition of PHMB antimicrobial agent to prevent bacterial penetration and colonization of the dressing.

Substantial equivalence is also claimed to Kerlix AMD and Excilon AMD, absorbent wound dressings which contain PHBM antimicrobial agent to prevent bacterial penetration and colonization of the dressing.

510(k) Premarket Notification
COPA AMD Antimicrobial Wound Dressing

Section B – 510(K) Summary

Device Description:

COPA AMD is a hydrophilic polyurethane foam that is impregnated with Polyhexamethylene Biguanide Hydrochloride (PHMB), an antimicrobial agent that protects the dressing from bacterial penetration and colonization.

Intended Use:

COPA AMD dressings are indicated for use in management of post-surgical incisions, pressure sores, venous stasis ulcers, diabetic ulcers, donor sites, abrasions, lacerations, 1st and 2nd degree burns, dermatologic disorders, other wounds inflicted by trauma and, as a secondary dressing or cover dressing for packed wounds.

Performance Data: Performance data submitted in support of this 510k included in-vitro and animal testing.

Broad spectrum activity was demonstrated against 6 organisms including gram positive, gram negative, and fungal types. Total kill was achieved for 7 consecutive days, with a daily challenge of >6 log of each organism:

- P. aeruginosa
- E. coli
- C. albicans
- S. epidermidis
- S. aureus
- E. faecalis

**INSTRUCTIONS FOR USE/ PACKAGE INSERT
COPA™ AMD™, COPA™ AMD™ PLUS, COPA™ AMD™ ISLAND**

™ Trademark of Tyco Healthcare Group LP or its affiliate

™ CONSTANT-CLENS is a trademark of Unilever Supply chain, Inc., and used under license

TYCO HEALTHCARE GROUP LP.MANSFIELD, MA 02048.MADE IN USA

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PRODUCT INFORMATION IN U.S. 1-800-962-9888-www.TycoHealthcare.com

EC REP TYCO HEALTHCFARE U.K. LTD. . Gosport PO13 OAS, U.K.

DESCRIPTION

COPA™ AMD™ Antimicrobial Foam Dressings™ provide an ideal moist wound healing environment for a wide variety of wounds. This highly absorbent, non-linting dressing is designed to protect and cushion moderate to heavily exuding wounds. COPA AMD Dressings are semi-occlusive allowing the exchange of gases such as oxygen and water vapor. The soft flexible nature of the COPA AMD dressing allows it to conform easily to all body contours. COPA AMD Dressings are non-adherent, and non-drying, making dressing changes easy and minimizing pain.

COPA AMD Dressings provide an antimicrobial barrier to bacteria penetration through the dressing and prevents colonization and proliferation of bacteria within the dressing for up to seven days. By limiting the microbial growth in wound exudates, the bioburden load on healing tissue is minimized.

INDICATIONS FOR USE

COPA AMD dressings are indicated for use in management of post-surgical incisions, pressure sores, venous stasis ulcers, diabetic ulcers, donor sites, abrasions, lacerations, 1st and 2nd degree burns, dermatologic disorders, other wounds inflicted by trauma and, as a secondary dressing or cover dressing for packed wounds. It is an ideal dressing in the local management of exudate that may occur at surgically induced body drainage sites such as tracheostomy, G-tube, J-tube, Penrose drain, chest tube, nephrotomy tube or sump drain.

**INSTRUCTIONS FOR USE/ PACKAGE INSERT
COPA™ AMD™, COPA™ AMD™ PLUS, COPA™ AMD™ ISLAND**

PRECAUTIONS

- For external use only
- Do not use as a primary treatment for infected wounds
- Do not use as a primary treatment for full 3rd degree burns
- Do not use on patients with known sensitivity to PHMB
- Do not use if primary package is damaged.
- Do not resterilize
- Single use only

PREPARING THE WOUND SITE

Cleanse the wound area if necessary using a non-toxic cleansing solution such as CONSTANT CLENS™ or saline. Rinse and dry the wound and surrounding areas thoroughly before dressing application.

APPLYING THE DRESSING

Select the dressing which will provide a minimum of a 2 inch (5 cm) foam margin around the edges of the wound. If necessary, cut the dressing to size to ensure a smooth, continuous fit with the skin surface. (COPA AMD Dressings should be applied with the white side touching the dressing site or with the topsheet facing up.)

Place COPA AMD Dressing directly onto the wound surface and hold in place by covering with POLYSKIN™ II Dressing, Kerlix™ or CURITY™ Gauze Bandage Rolls, TENSOR™ Elastic Bandage, CONFORM™ Stretch Bandage, adhesive tape or other appropriate secondary dressing. If using COPA AMD Island Dressings, use of the above mentioned products will not be needed to hold the dressing in place.

FREQUENCY OF CHANGE

The high absorbency and sustained antimicrobial efficacy of COPA AMD Dressings allows the user to comply with established treatment protocols for

INSTRUCTIONS FOR USE/ PACKAGE INSERT
COPA™ AMD™, COPA™ AMD™ PLUS, COPA™ AMD™ ISLAND

foam dressings, up to one week between dressing changes.. In typical use, the frequency of changes will depend upon the nature and condition of the wound and the amount of exudate.

DRESSING CHANGE AND REMOVAL

The COPA™ AMD™ Dressing should be changed when signs of saturation are visible along the edge of the dressing or whenever good nursing practice dictates. To change the dressing, remove the securing bandages or tape and carefully lift COPA AMD Dressing off the wound. COPA AMD Dressings are non-adherent, non- adhesive, and non-gelling.

DRESSING EXPANSION

COPA AMD Dressings absorb exudate and will expand and 'grow' in size due to the cellular structure of the dressing.

ORDERING INFORMATION

<i>REF</i>	<i>Description</i>	<i>Quantity per Carton</i>	<i>Quantity per Carton</i>
<u>COPA™ AMD™ Antimicrobial Foam Dressing</u>			
55522AMD	2 in X 2 in COPA AMD Foam Dressing	25	100
55544AMD	4 in X 4 in COPA AMD Foam Dressing	10	50
55566AMD	6 in X 6 in COPA AMD Foam Dressing	10	50
55535AMD	3 ½ in X 3 in COPA AMD Fenestrated Foam Dressing	10	50
55511AMD	1" Diameter COPA AMD Fenestrated Foam Dressing	10	50
<u>COPA™ AMD™ PLUS Antimicrobial Foam Dressing</u>			
55544PAMD	4 in x 4 in COPA AMD PLUS Foam Dressing	10	50
<u>COPA™ AMD™ Island Antimicrobial Foam Dressing</u>			
55522AMD	4 in X 4 in Pad Size	10	50
55544AMD	6 in X 6 in Pad Size	10	50

21⁶³

Indications for Use Statement

510(k) number: K071371

Device Name:

COPA AMD antimicrobial wound dressing

Indications for Use:

COPA AMD dressings are indicated for use in management of post-surgical incisions, pressure sores, venous stasis ulcers, diabetic ulcers, donor sites, abrasions, lacerations, 1st and 2nd degree burns, dermatologic disorders, other wounds inflicted by trauma and, as a secondary dressing or cover dressing for packed wounds.

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)

Appendix 6 (new)

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QA / SCIENTIFIC SERVICES

ELUTION STUDY PROTOCOL ADDENDUM

TITLE: **Elution Study of PHMB from COPA AMD and Kerlix AMD**

Protocol No. (b) (4) _____ 1

August 1, 2007

Written By: *Sara Gordon* Date: 8/1/07
Sara Gordon, Scientific Services

Reviewed By: *Ann Sung* Date: 8/1/07
Ann Sung, Scientific Services

Approved By: *Bob Almeida* Date: 8/1/07
Bob Almeida, Scientific Services

TYCO / HEALTHCARE / KENDALL COMPANY

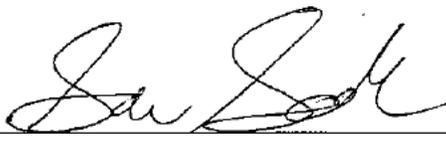
QA / SCIENTIFIC SERVICES

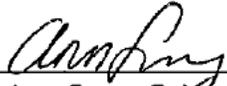
ELUTION STUDY PROTOCOL

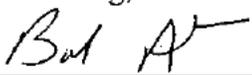
TITLE: **Elution Study of PHMB from COPA AMD and Kerlix AMD**

Protocol No.: (b) (4) 

July 30, 2007

Written By:  Date: 7/30/07
Sara Gordon, Scientific Services

Reviewed By:  Date: 7/30/07
Ann Sung, Scientific Services

Approved By:  Date: 7/30/07
Bob Almeida, Scientific Services

Appendix 7 (new)

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

November 07, 2007

TYCO HEALTHCARE GROUP, LP
15 HAMPSHIRE ST.
MANSFIELD, MA 02048
ATTN: JAMES WALSH

510(k) Number: K071371
Product: COPA AMD
ANTIMICROBIAL
WOUND DRESSING

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1567.html>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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

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

Sincerely yours,

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

tyco

Healthcare

Kendall

K071371/S2

15 Hampshire Street
Mansfield, MA 02048

Tel: 508-261-8000
Fax: 508-261-8461

www.kendallhq.com

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

November 2, 2007

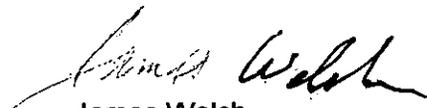
RE: 510(k) # K071371 Premarket Notification for COPA AMD Antimicrobial Foam Wound Dressing

Dear Dr. Arepalli:

This letter is in response to the deficiency letter dated October 3rd, 2007, as clarified in our phone conversation of October 5th, 2007. For ease of reading, I have restated each question followed by the response. For some questions, revised pages are included. For other questions, new information is provided in the appendices to this letter, and the numbering of these appendices begins at #8, so as not to duplicate the numbering in the original submission.

Please contact the undersigned at (508) 261-8532 should you have any additional questions.

Sincerely,



James Welsh
Vice President, Regulatory Affairs
Tyco Healthcare/Kendall

Enclosure

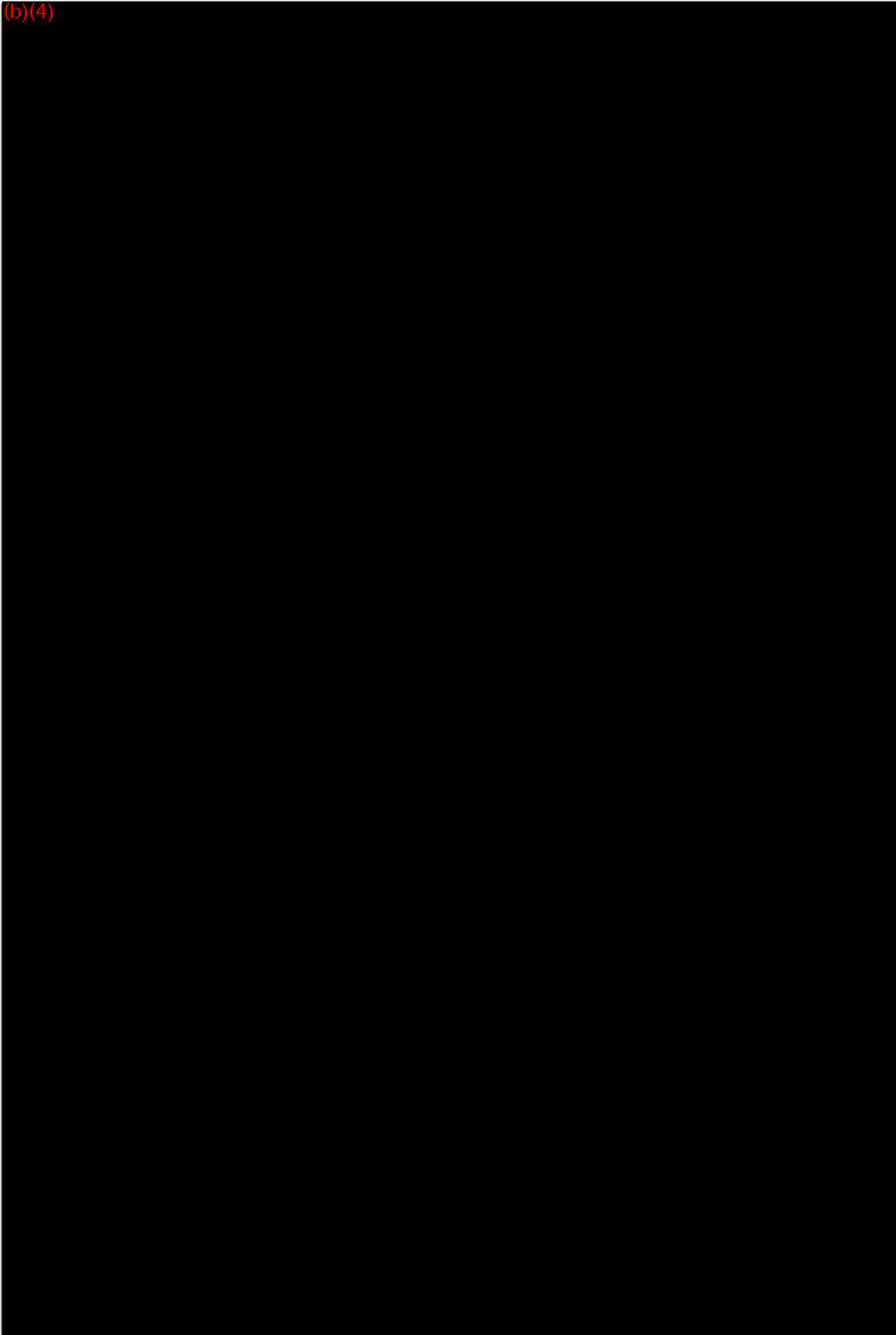
FDA CDRH DMC

NOV 07 2007

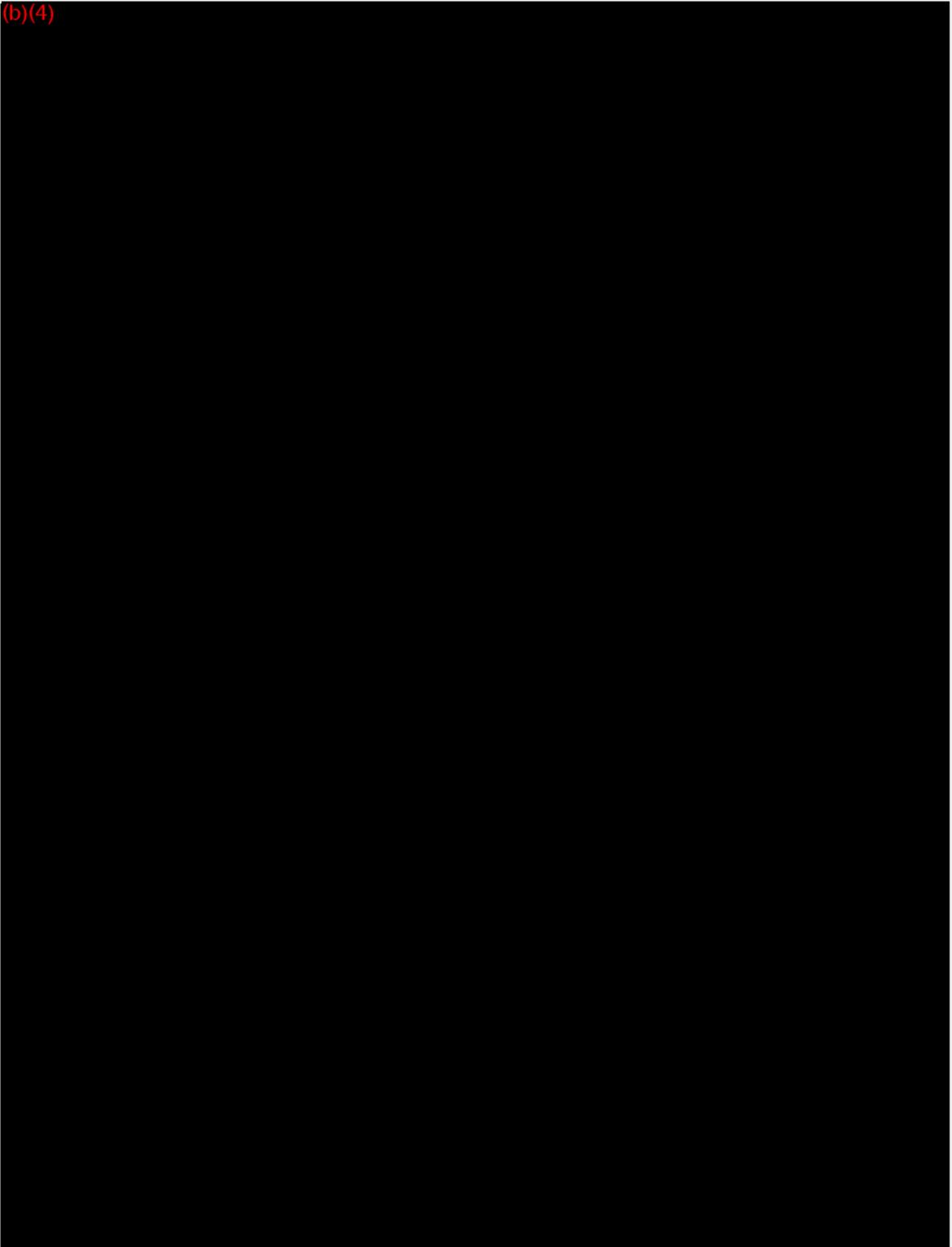
Received

K20

(b)(4)



(b)(4)





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REF

55588BAMD

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COPA™ AMD™ ISLAND

Adhesive Bordered Antimicrobial Foam Dressing

8" x 8" (20 cm x 20 cm)

Pansement hydrocellulaire antimicrobien avec bordure adhésive
Antimikrobieller Schaumstoffverband mit Hafttrand
Medicazione antimicrobica in schiuma con bordi adesivi
Apósito de espuma antimicrobiano con bordes adhesivos
Antimikrobiellt skumförband med självhäftande kanter
Antimicrobieel schuimverband met plakkende rand
Penso de espuma antimicrobiana com bordo adesivo
Limareunainen antimikrobinen vaahdotuovuisidos
Antimikrobiel skumbandage med selvklæbende kanter
Αντιμικροβιακό αφρώδες επίθεμα με αυτοκόλλητο περιθώριο

ALLERGEN POTENTIAL

Do not use on patients with known sensitivity to PHMB
PHMB exposure in high concentrations (≥2.5%) has been infrequently
associated with contact dermatitis. If dermatitis is observed, discontinue use.

STERILE EO



Single Use



See Accompanying Documents



Keep Away From Sunlight



RX ONLY



Do not use if unit package is opened or damaged.
Do not use if unit package is opened or damaged.
Do not use if unit package is opened or damaged.



Contains 0.5% Polyhexamethylene Biguanide HCl (PHMB)

Enthält 0.5 % PHMB
Contiene 0.5% PHMB
Contiene 0.5% PHMB
Innehåller 0.5 % PHMB
Berat 0.5% PHMB
Contém 0.5% de PHMB
Sisältää 0.5 % PHMB:ta
Innehåller 0.5% PHMB
Περιέχει 0.5% PHMB



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Shipping Case

10/26/07

COPA™ AMD™ ISLAND



REF 55588BAMD

8" x 8"
(20 cm x 20 cm)

Adhesive Bordered Antimicrobial Foam Dressings
Pansement hydrocellulaire antimicrobien avec bordure adhésive

Antimikrobieller Schaumstoffverband mit Hafttrand

Medicazione antimicrobica in schiuma con bordi adesivi

Apósito de espuma antimicrobiano con bordes adhesivos

Antimikrobiell skumförband med självhäftande kanter

Penso de espuma antimicrobiana com bordo adesivo

Limareunainen antimikrobinen vaahdonmuovisidos



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COPA™ AMD™ ISLAND



REF 55588BAMD

8" x 8"
(20 cm x 20 cm)



50

Contains Polyhexamethylene biguanide hydrochloride (PHMB), 0.5%

ALLERGEN POTENTIAL

Do not use on patients with known sensitivity to PHMB
PHMB exposure in high concentrations ($\geq 2.5\%$) has been infrequently
associated with contact dermatitis. If dermatitis is observed, discontinue use.

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COPA™ AMD™ ISLAND

Adhesive Bordered Antimicrobial Foam Dressings

8" X 8" (20 cm X 20 cm)

Pansement hydrocellulaire antimicrobien avec bordure adhésive
Antimikrobieller Schaumstoffverband mit Hafttrand
Medicazione antimicrobica in schiuma con bordi adesivi
Apósito de espuma antimicrobiano con bordes adhesivos
Antimikrobiellit skumförband med självhäftande kanter
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Penso de espuma antimicrobiana com bordo adesivo
Limareunainen antimikrobinen vaahdonmuovisidos
Antimikrobieel skumbandage med selvklæbende kanter
Αντιμικροβιακό αφρώδες επίθεμα με αυτοκόλλητο περιθώριο

Contains 0.5% Polyhexamethylene Biguanide HCl (PHMB)

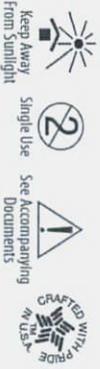
- Contient 0.5 % de PHMB
Enthält 0.5 % PHMB
Contiene 0.5% PHMB
Contiene 0.5% PHMB
Innehåller 0.5 % PHMB
Bevat 0.5% PHMB
Contém 0.5% de PHMB
Sisältää 0.5 % PHMB:ta
Indeholder 0.5% PHMB
Περιέχει 0.5% PHMB

ALLERGEN POTENTIAL

Do not use on patients with known sensitivity to PHMB
PHMB exposure in high concentrations (≥2.5%) has been infrequently associated with contact dermatitis. If dermatitis is observed, discontinue use.

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Do not use if unit package is opened or damaged.



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Side



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COPA™ AMD™ ISLAND

Adhesive Bordered Antimicrobial Foam Dressings

8" X 8" (20 cm X 20 cm)

Pansement hydrocellulaire antimicrobien avec bordure adhésive
Antimikrobieller Schaumstoffverband mit Hafttrand
Medicazione antimicrobica in schiuma con bordi adesivi
Apósito de espuma antimicrobiano con bordes adhesivos
Antimikrobiellit skumförband med självhäftande kanter
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Limareunainen antimikrobinen vaahdonmuovisidos
Antimikrobieel skumbandage med selvklæbende kanter
Αντιμικροβιακό αφρώδες επίθεμα με αυτοκόλλητο περιθώριο

LOT

INSTRUCTIONS FOR USE/ PACKAGE INSERT
COPA™ AMD™, COPA™ AMD™ PLUS, COPA™ AMD™ ISLAND

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EC REP TYCO HEALTHCFARE U.K. LTD. . Gosport PO13 OAS, U.K.

DESCRIPTION

COPA™ AMD™ Antimicrobial Foam Dressings provide an ideal moist wound healing environment for a wide variety of wounds. This highly absorbent, non-linting dressing is designed to protect and cushion moderate to heavily exuding wounds. COPA AMD Dressings are semi-occlusive allowing the exchange of gases such as oxygen and water vapor. The soft flexible nature of the COPA AMD dressing allows it to conform easily to all body contours. COPA AMD Dressings are non-adherent, and non-drying, making dressing changes easy and minimizing pain.

COPA AMD Dressings contain the antimicrobial agent Polyhexamethylene biguanide hydrochloride (PHMB), and provide an antimicrobial barrier to bacteria penetration through the dressing and prevents colonization and proliferation of bacteria within the dressing for up to seven days.

INDICATIONS FOR USE

COPA AMD dressings are indicated for use in management of post-surgical incisions, pressure sores, venous stasis ulcers, diabetic ulcers, donor sites, abrasions, lacerations, 1st and 2nd degree burns, dermatologic disorders, other wounds inflicted by trauma and, as a secondary dressing or cover dressing for packed wounds. It is an ideal dressing in the local management of exudate that may occur at surgically induced body drainage sites such as tracheostomy, G-tube, J-tube, Penrose drain, chest tube, nephrotomy tube or sump drain.

INSTRUCTIONS FOR USE/ PACKAGE INSERT
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PRECAUTIONS

- For external use only
- Do not use as a primary treatment for infected wounds
- Do not use as a primary treatment for full 3rd degree burns
- Do not use on patients with known sensitivity to PHMB
- Do not use if primary package is damaged.
- Do not resterilize
- Single use only

ALLERGEN POTENTIAL

PHMB exposure in high concentrations ($\geq 2.5\%$) has been infrequently associated with contact dermatitis. If dermatitis is observed, discontinue use.

PREPARING THE WOUND SITE

Cleanse the wound area if necessary using a non-toxic cleansing solution such as CONSTANT CLENS™ or saline. Rinse and dry the wound and surrounding areas thoroughly before dressing application.

APPLYING THE DRESSING

Select the dressing which will provide a minimum of a 2 inch (5 cm) foam margin around the edges of the wound. If necessary, cut the dressing to size to ensure a smooth, continuous fit with the skin surface. (COPA AMD Dressings should be applied with the white side touching the dressing site or with the topsheet facing up.)

Place COPA AMD Dressing directly onto the wound surface and hold in place by covering with POLYSKIN™ II Dressing, Kerlix™ or CURITY™ Gauze Bandage Rolls, TENSOR™ Elastic Bandage, CONFORM™ Stretch Bandage, adhesive tape or other appropriate secondary dressing. If using COPA AMD Island Dressings, use of the above mentioned products will not be needed to hold the dressing in place.

**INSTRUCTIONS FOR USE/ PACKAGE INSERT
COPA™ AMD™, COPA™ AMD™ PLUS, COPA™ AMD™ ISLAND**

FREQUENCY OF CHANGE

The high absorbency and sustained antimicrobial efficacy of COPA AMD Dressings allows the user to comply with established treatment protocols for foam dressings, up to one week between dressing changes.. In typical use, the frequency of changes will depend upon the nature and condition of the wound and the amount of exudate.

DRESSING CHANGE AND REMOVAL

The COPA™ AMD™ Dressing should be changed when signs of saturation are visible along the edge of the dressing or whenever good nursing practice dictates. To change the dressing, remove the securing bandages or tape and carefully lift COPA AMD Dressing off the wound. COPA AMD Dressings are non-adherent, non- adhesive, and non-gelling.

DRESSING EXPANSION

COPA AMD Dressings absorb exudate and will expand and 'grow' in size due to the cellular structure of the dressing.

Shipping Case

10/26/07

28

COPA™ AMD™ ISLAND

REF 55588BAMD
8" x 8"
(20 cm x 20 cm)

Adhesive Bordered Antimicrobial Foam Dressings
Pansement hydrocellulaire antimicrobien avec bordure adhésive
Antimikrobieller Schaumstoffverband mit Haftband
Medicazione antimicrobica in schiuma con bordi adesivi
Apósito de espuma antimicrobiano con bordes adhesivos
Antimikrobiell skumband med självhäftande kanter
Antimicrobiciel schuimverband met plakkende rand
Penso de espuma antimicrobiana com bordo adesivo
Līmareunainen antimikrobinen vaahatomuovisidos

 **50**

STERILE EO

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Single Use

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(01)30694393109900



(10)000000

COPA™ AMD™ ISLAND

REF 55588BAMD
8" x 8"
(20 cm x 20 cm)

Antimikrobiell skumbandage med selvkæbende kanter
Αντιμικροβιακό αφρώδες ετιθέζα με αυτοκόλλητο περιθώριο
Antimikrobiální pěnové krytí s adhezivním okrajem
Ragasztós széű antimikrobiális habszivacsokétszer
Антимикробная повязка из полиуретановой губки с клейкими краями
Przeciwbakteryjny opratunek piankowy z samoprzylepnym obrotowaniem
Yapışkan Kenarlı Antimikrobik Köpük Yara Örtüsü
Antimikrobiell skumbandasje med selvhæftende kanter

0.5% Polyhexamethylene Biguanide HCl (PHMB)

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COPA™ AAMD™ ISLAND

Adhesive Bordered Antimicrobial Foam Dressings

INDICATIONS: Post-surgical incisions, pressure sores, venous stasis ulcers, diabetic ulcers, donor sites, abrasions, lacerations, superficial burns...

INDIKATIONEN: Postoperatieve incisionen, Drukgeschwüre, Venenstauungsläsionen, diabetische Ulzeraationen, Eintraumestellen...

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0.5% PHMB



540506834007884



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Single Use



See Accompanying Documents



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(01) 20694393109903

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10



8" X 8" (20 cm X 20 cm)

Adhesive Bordered Antimicrobial Foam Dressings

COPA™ AAMD™ ISLAND

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side

29

Pansement hydrocellulaire antimicrobien avec bordure adhésive - Antimicrobiiell skumverband med klebende kant...

Front of Box



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COPA™ AAMD™ ISLAND

Adhesive Bordered Antimicrobial Foam Dressings

8" x 8" (20 cm x 20 cm)

Pansement hydrocellulaire antimicrobien avec bordure adhésive
Antimikrobieller Schaumstoffverband mit Hafttrand
Medicazione antimicrobica in schiuma con bordi adesivi
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Antimicrobiell schaumverband met plakkende rand
Penso de espuma antimicrobiana com bordo adesivo
Limaareunainen antimikrobinen vaahdonmuovisidos
Antimikrobiel skumbandage med selvklebende kanter
Αντιμικροβιακό αφρώδες επιθελα με αυτοκόλλητο περιθώριο
Αντιμικροβιακό αφρώδες επιθελα με αυτοκόλλητο περιθώριο
Antimikrobiell skumbandasje med selvhæftende kanter

Contains 0.5% Polyhexamethylene Biquanide HCl (PHMB)

Content 0.5 % de PHMB
Enthält 0.5 % PHMB
Contiene 0.5% PHMB
Contiene 0.5% PHMB
Innehåller 0.5 % PHMB
Beval 0.5% PHMB
Contém 0.5% de PHMB
Sisältää 0.5 % PHMB:ta
Inneholder 0.5% PHMB
Περιέχει 0.5% PHMB
Obsahuje 0.5 % polyhexametylenbiquanidu (PHMB)
Contiene 0.5% polihexametilen biquanida
Zawiera 0.5% PHMB
9%0.5 PHMB ięci.
Inneholder 0.5 % PHMB

Side



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KENDALL

COPA™ AAMD™ ISLAND

Adhesive Bordered Antimicrobial Foam Dressings

8" x 8" (20 cm x 20 cm)

Pansement hydrocellulaire antimicrobien avec bordure adhésive
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Antimikrobiel skumbandage med selvklebende kanter
Αντιμικροβιακό αφρώδες επιθελα με αυτοκόλλητο περιθώριο
Αντιμικροβιακό αφρώδες επιθελα με αυτοκόλλητο περιθώριο
Antimikrobiell skumbandasje med selvhæftende kanter

LOT



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COPA™ AMD™ ISLAND

Adhesive Bordered Antimicrobial Foam Dressing

8" x 8" (20 cm x 20 cm)

Pansement hydrocellulaire antimicrobien avec bordure adhésive
 Antimikrobieller Schaumstoffverband mit Hafttrand
 Medicazione antimicrobica in schiuma con bordi adesivi
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 Αντιμικροβιακό αφρώδες επίθεμα με αυτοκόλλητο περιθώριο
 Antimikrobiální pěnové krytí s adhezívním okrajem
 Ragasztós szélű antimikrobiális habszivacsoktószer
 Antimikrobiální pěnové krytí s adhezívním okrajem
 Антимикробная повязка из полиуретановой губки с клейкими краями
 Przeciwbakteryjny opatrunek piankowy z samoprzylepnym obramowaniem
 Yarışkan Kenarlı Antimikrobiel Köpük Yara örtüsü
 Antimikrobiell skumbandasje med selvheftende kanter

Contains 0.5% Polyhexamethylene Biguanide HCl (PHMB)

Contient 0.5 % de PHMB
 Enthält 0.5 % PHMB
 Contiene 0.5% PHMB
 Contiene 0.5% PHMB
 Innehåller 0.5 % PHMB
 Bevat 0.5% PHMB
 Contém 0.5% de PHMB
 Sisältää 0.5 % PHMB:ta
 Inneholder 0.5% PHMB
 Περιέχει 0.5% PHMB
 Obsahuje 0.5 % polyhexametylenbiguanidu (PHMB)
 0.5% PHMB-t tartalmaz.
 Содержит 0.5% полигексаметилен бигуанида
 Zawiera 0.5% PHMB
 %0.5 PHMB içerir.
 Inneholder 0.5 % PHMB



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Single Use See Accompanying Documents



Keep Away From Sunlight



RX ONLY



- Do not use if unit package is opened or damaged. - Ne pas utiliser si l'emballage a été ouvert ou endommagé. Bei geöffneter oder beschädigter Verpackung nicht verwenden. - Non usare il prodotto se la confezione è aperta o danneggiata. - No usar si el envase está abierto o dañado. - Använd inte om enhetens förpackning är öppnad eller skadad. - Niet gebruiken indien verpakking geopend of beschadigd is. - Não usar se a embalagem estiver aberta ou danificada. - Ei saa käyttää, jos pakkaus on avattu tai vaurioitunut. - Ad ikke anvendes, hvis emballagen er åbnet eller beskadiget. - Μη χρησιμοποιείτε αν η συσκευασία έχει ανοίξει ή υποστεί ζημιά. - Pokud je balení otevřené nebo poškozené, výrobek nepoužívejte. - Tilos használni, ha felfürt vagy megsérült a csomagolás. - He използвайте изданието, если упаковка вскрыта или повреждена. - Nie stosować, jeżeli opakowanie zostało otwarte lub uszkodzone. - Urünün ambalajı açılmışsa ya da hasarlıysa kullanılmayın.

Patent Pending
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Pouch label