



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 29, 2010

POLYREMEDY, INC.
24372 MCCLOUD COURT
LAGUNA NIGUEL, CALIFORNIA 92677
UNITED STATES
ATTN: GARY MOCNIK

510k Number: K092351

Product: POLY FIT + ABSORBING AND HIGH

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 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 <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. 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/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. 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.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

K092351/S1



March 26, 2010

FDA CDRH DMC

MAR 29 2010

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Received

K-11

Attn: David Krause, Ph.D., George Ngatha

Re: K092351

Trade Name: Poly Fit + Absorbing & High Absorbing Antimicrobial Dressings
Email communication dated October 20, 2009

Dear Sirs:

The following is in response to your email communication dated October 20, 2009 requesting additional information necessary to complete the review of the above reference premarket notification. We have repeated the original request in italics followed by the specific response.

We appreciate the agency's consideration and review of this submission and if there are any questions regarding this information, please do not hesitate to contact me at (949) 433-0413.

Please also note that PolyRemedy has retained Jonathan Kahan, of Hogan & Hartson, L.L.P. as regulatory counsel to assist in this 510(k) submission. Please accept this correspondence as the company's authorization for Mr. Kahan and his firm to discuss this submission with FDA on behalf of PolyRemedy.

Sincerely,

(b)(6)

Gary Mocnik
Official Correspondent
Poly Remedy, Inc.

(b)(4)

(b)(4)

Sincerely,

(b)(6)

Gary Mocnik

2637 Marine Way, Suite 100
Mountain View, California 94043
P: 650.960.2404
F: 650.960.2406
M: **(b)(6)**
garym@polyremedy.com

Attachment 1

(b)(4)

6. 510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMMA 1990 and 21 CFR 807.92.

APPLICANT:	PolyRemedy, Inc.
TRADE NAME:	Poly FIT™+ Absorbing Antimicrobial Dressings Poly FIT™+ High Absorbing Antimicrobial Dressings
COMMON NAME:	Wound Dressing
CLASSIFICATION NAME:	Dressing, Wound, Drug
DEVICE CLASSIFICATION:	Unclassified (preamendment)
PRODUCT CODE	FRO
PREDICATE DEVICES:	PolyFIT Absorbing and PolyFIT High Absorbing Wound Dressings (510k exempt; NAC) COPA AMD Antimicrobial Wound Dressing (K071371, K082296)

Substantially Equivalent To:

PolyFIT+ Absorbing Antimicrobial Dressings are substantially equivalent in intended use, principal of operation and technological characteristics to the legally marketed PolyFIT Absorbing Wound Dressing (510k exempt) and the COPA AMD Antimicrobial Wound Dressing (K071371).

Description of the Device Subject to Premarket Notification:

PolyFIT+ Absorbing Antimicrobial Dressings are soft, sterile dressings designed for the management of exuding wounds and are intended as effective barriers to inhibit microbial proliferation within the dressing and reduce microbial penetration through the dressing. PolyFIT+ Absorbing Antimicrobial Dressings are made of synthetic, hydrophilic, fibers embedded with a 0.3% concentration of Polyhexamethylene Biguanide (PHMB).

PolyRemedy employs an electrospinning process to manufacture the ingredients: polyethylene oxide (PEO), polyethylene-co-vinyl-alcohol (EVOH), polycaprolactone (PCL) and PHMB into fibers, forming consistent and congruent dressings. Within the PolyFIT+ Absorbing Antimicrobial Dressings, the PEO gelling fibers are supported by the EVOH and PCL fibers for structural integrity. While absorbing wound exudate, the fibers transform from a dry dressing into a fiber gelling dressing that rapidly absorbs excess exudate away from the wound surface and retains it in the dressing. When exudate is absorbed into the PolyFIT+ Absorbing Antimicrobial Dressing, the PHMB embedded in the fibers ensures that when bacteria come in contact with the PHMB molecule the outer cell wall of the bacteria is disrupted,

PolyRemedy, Inc.

PolyFIT + Absorbing Antimicrobial Dressings

Premarket Notification

Section 6**510(k) Summary of Safety and Effectiveness**

resulting in leakage of cytoplasm and cell death. As a consequence, bacterial numbers decrease, replication ceases and mutation cannot occur.

Indication for Use:

PolyFIT+ Absorbing Antimicrobial Dressings are intended as effective barriers to inhibit microbial proliferation within the dressing and reduce microbial penetration through the dressing. PolyFIT+ Absorbing Antimicrobial Dressings are for use under a healthcare professional's orders as adjunctive treatment in the management of exudating wounds, partial and full-thickness wounds, such as pressure ulcers (Stages II-IV), lower extremity ulcers (venous or arterial), diabetic foot ulcers, surgical or traumatic wounds (including those left open to heal by secondary intention). They are not intended for wounds with exposed tendon or bone, for 3rd degree burns or for dry wounds.

Technical Characteristics:

PolyFIT+ Absorbing Antimicrobial Dressings have similar physical and technical characteristics to the predicate devices.

Performance Data:

All necessary verification and validation testing has been performed for the PolyFIT+ Absorbing Antimicrobial Dressings to assure substantial equivalence to the predicate devices.

Basis for Determination of Substantial Equivalence:

Upon reviewing the safety and effectiveness information provided in this submission and comparing intended use, principle of operation and overall technological characteristics, the PolyFIT+ Absorbing Antimicrobial Dressings are determined by PolyRemedy to be substantially equivalent to existing legally marketed devices.

11. Executive Summary

Device Description

PolyFIT+ Antimicrobial Absorbing Wound Dressings

PolyFIT+ Absorbing Antimicrobial Dressings are soft, sterile dressings designed for the management of exudating wounds and are intended as effective barriers to inhibit microbial proliferation within the dressing and reduce microbial penetration through the dressing. PolyFIT+ Absorbing Antimicrobial Dressings are made of synthetic, hydrophilic fibers permanently embedded with a 0.3% concentration of polyhexamethylene biguanide (PHMB) and an outer protecting layer.

PolyRemedy employs an electrospinning process to manufacture the ingredients: polyethylene oxide (PEO), polyethylene-co-vinyl-alcohol (EVOH), PHMB and polycaprolactone (PCL) into fibers, forming consistent and congruent dressings. Within the PolyFIT+ Absorbing Antimicrobial Dressings, the PEO gelling fibers are supported by the EVOH and PCL fibers for structural integrity. While absorbing wound exudate, the fibers transform from a dry dressing into a fiber gelling dressing that rapidly absorbs excess exudate away from the wound surface and retains it in the dressing. When exudate is absorbed into the PolyFIT+ Absorbing Antimicrobial Dressing, the PHMB embedded in the fibers ensures that when bacteria come in contact with the PHMB molecule the outer cell wall of the bacteria is disrupted resulting in leakage of cytoplasm and cell death. As a consequence bacterial numbers decrease, replication ceases and mutation cannot occur.

The PolyFIT+ Absorbing Antimicrobial Dressings will be marketed as a finished medical device in three sizes (2x2, 4x4, and 5x5 inches) and two types (PolyFIT+ Absorbing Antimicrobial Dressings and PolyFIT+ High Absorbing Antimicrobial Dressings).

The Dressings are packaged in a foil, peel-open pouch. Both dressing and pouch materials are terminally sterilized by gamma radiation.

Intended Use

PolyFIT+ Absorbing Antimicrobial Dressings are intended as an effective barrier to inhibit microbial proliferation within the dressing and reduce microbial penetration through the dressing. PolyFIT+ Absorbing Antimicrobial Dressings are for use under a healthcare professional's orders as adjunctive treatment in the management of exudating wounds, partial and full-thickness wounds, such as pressure ulcers (Stages II-IV), lower extremity ulcers (venous or arterial), diabetic foot ulcers, surgical or traumatic wounds (including those left open to

heal by secondary intention). They are not intended for wounds with exposed tendon or bone, for 3rd degree burns or for dry wounds.

Predicate Devices

PolyFIT+ Absorbing Antimicrobial Dressings are substantially equivalent in intended use, principal of operation and technological characteristics to the PolyFIT Absorbing Wound Dressing (510k exempt) and the COPA AMD Antimicrobial Wound Dressing (K071371).

A summary of the substantial equivalence between the PolyFIT+ Antimicrobial Absorbing Wound Dressings and the identified predicates is found in the table below.

Table 11.1 - Substantial Equivalence

	PolyFIT+ Absorbing Antimicrobial Dressings	PolyFIT Absorbing Wound Dressings	COPA AMD Antimicrobial Wound Dressings
Intended Use	PolyFIT+ Absorbing Antimicrobial Dressings are intended as effective barriers to inhibit microbial proliferation within the dressing and reduce microbial penetration through the dressing. PolyFIT+ Absorbing Antimicrobial Dressings are for use under a healthcare professional's orders as adjunctive treatment in the management of exudating wounds, partial and full-thickness wounds, such as pressure ulcers (Stages II-IV), lower extremity ulcers (venous or arterial), diabetic foot ulcers, surgical or traumatic wounds (including those left open to heal by secondary intention). They are not intended for wounds with exposed tendon or	Indicated for use under a healthcare professional's orders as adjunctive treatment in the management of exudating wounds, partial and full-thickness wounds, such as pressure ulcers (Stages II-IV), lower extremity ulcers (venous or arterial), diabetic foot ulcers, surgical or traumatic wounds (including those left open to heal by secondary intention). They are not intended for wounds with exposed tendon or bone, for 3 rd degree burns or for dry wounds.	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.

Section 11**Executive Summary**

	PolyFIT+ Absorbing Antimicrobial Dressings	PolyFIT Absorbing Wound Dressings	COPA AMD Antimicrobial Wound Dressings
	bone, for 3 rd degree burns or for dry wounds.		
Principal of Operation	Absorbs and retains wound exudate	Absorbs and retains wound exudate	Absorbs and retains wound exudate
Overall Technological Characteristics	Non-resorbable matrix with hydrophilic properties and antimicrobial agent (PHMB) embedded within the dressing fibers	Non-resorbable matrix with hydrophilic properties	Non-resorbable matrix with hydrophilic properties and antimicrobial agent (PHMB)

Performance Testing

Performance testing was conducted for the PolyFIT+ Absorbing Antimicrobial Dressings to demonstrate the integrity and suitability of the device for its intended use. The results of the testing indicate that PolyFIT+ Absorbing Antimicrobial Dressing are substantially equivalent to the predicate devices and are safe and effective for their intended use.

12. Device Description

PolyFIT+ Absorbing Antimicrobial Dressings are soft, sterile dressings designed for the management of exuding wounds and are intended as effective barriers to inhibit microbial proliferation within the dressing and reduce microbial penetration through the dressing. PolyFIT+ Absorbing Antimicrobial Dressings are made of synthetic, hydrophilic fibers permanently embedded with a 0.3% concentration of Polyhexamethylene Biguanide (PHMB) and an outer protecting layer.

Within the PolyFIT+ Absorbing Antimicrobial Dressings the PEO (poly ethylene oxide) gelling fibers are supported by the EVOH (ethylene co-vinyl alcohol) and PCL (polycaprolactone) fibers for structural integrity, and allow for simple one-piece removal from the wound. While absorbing wound exudate, the fibers transform from a dry dressing into a fiber gelling dressing that rapidly absorbs excess exudate away from the wound surface and retains it in the dressing. When exudate is absorbed into the PolyFIT+ Absorbing Antimicrobial Dressing, the PHMB embedded in the fibers ensures that when bacteria come in contact with the PHMB molecule the outer cell wall of the bacteria is disrupted resulting in leakage of cytoplasm and cell death. As a consequence, bacterial numbers decrease, replication ceases and mutation cannot occur.

The PolyFIT+ Absorbing Antimicrobial Dressings will be marketed as a finished medical device in three sizes (2x2, 4x4, and 5x5 inches) and two types (PolyFIT+ Absorbing Antimicrobial Dressings and PolyFIT+ High Absorbing Antimicrobial Dressings).

The Dressings are packaged in a foil, peel-open pouch. Both dressing and pouch materials are terminally sterilized by gamma radiation.

Rationale for adding agent to device

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Materials of Construction

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Mechanism of Action

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Dressing Construction

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Device Operation and Features

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As demonstrated by a series of *in vitro* tests, PHMB has no adverse effect on the performance characteristics of the wound dressing. The antimicrobial performance of the PolyFIT+ Absorbing Antimicrobial Dressings was quantified through a series of standardized tests using challenge organisms commonly seen in soft tissue chronic wounds (see section 19).

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Section 11

Executive Summary

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Section 12

Device Description

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Attachment 2

Functional test results

	DOCUMENT NUMBER: (b)(4)	
	DOCUMENT TYPE: DESIGN REPORT	REV: (b)(4)
	ABSORBENCY TESTING OF (b)(4) AGED POLYFIT WOUND DRESSINGS WITH PHMB	

Author / Revised by:	
(b)(4)	

The user of any printed copy of this document is responsible for verifying it is the current revision prior to use.

Confidential Information

PAGE 1 OF 8

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

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Attachment 3

- Real time aged antimicrobial test reports

	DOCUMENT NUMBER: (b)(4)	
	DOCUMENT TYPE: DESIGN REPORT	REV: (b)(4)
	ANTIMICROBIAL TEST REPORT FOR REAL TIME AGED POLYFIT [®] ABSORBING ANTIMICROBIAL DRESSINGS	

Author / Revised by:	
----------------------	--

(b)(4)

The user of any printed copy of this document is responsible for verifying it is the current revision prior to use.

PolyRemedy Confidential

PAGE 1 OF 11

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5. Indications for Use Statement

K092351 1/1

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K092351Device Name: **PolyFIT™+ Absorbing Antimicrobial Dressings and PolyFIT™+ High Absorbing Antimicrobial Dressings**

Indications for Use:

PolyFIT+ Absorbing Antimicrobial Dressings are intended as effective barriers to inhibit microbial proliferation within the dressing and reduce microbial penetration through the dressing. PolyFIT+ Absorbing Antimicrobial Dressings are for use under a healthcare professional's orders as adjunctive treatment in the management of exudating wounds, partial and full-thickness wounds, such as pressure ulcers (Stages II-IV), lower extremity ulcers (venous or arterial), diabetic foot ulcers, surgical or traumatic wounds (including those left open to heal by secondary intention). They are not intended for wounds with exposed tendon or bone, for 3rd degree burns or for dry wounds.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krane

(Division Sign-Off)

Division of Surgical, Orthopedic,
and Restorative Devices510(k) Number K092351

Page 1 of _____



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

August 05, 2009

POLYMEDCO, INC.
C/O GARY MOCNIK
24372 MCCLOUD CT.
LAGUNA NIGUEL, CALIFORNIA 92677
UNITED STATES
ATTN: GARY MOCNIK

510k Number: K092351

Received: 8/4/2009

Product: POLY FIT + ABSORBING AND HIGH

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

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

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm>

for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm>.

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

Product, and Device Applications/Submissions. Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007”
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm>. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, “Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements”. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html>. In addition, the 510(k) Program Video is now available for viewing on line at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm>.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

6. 510(k) Summary of Safety and Effectiveness

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PolyRemedy, Inc.
PolyFIT + Absorbing Antimicrobial Dressings

Premarket Notification

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PolyRemedy, Inc.
PolyFIT + Absorbing Antimicrobial Dressings

Premarket Notification

**Appendix 1.1
COPA AMD
K071371**

PolyRemedy, Inc.
PolyFIT+ Absorbing Antimicrobial Dressings

Premarket Notification

510(k) Premarket Notification

[510\(k\)](#) | [Registration & Listing](#) | [Adverse Events](#) | [PMA](#) | [Classification](#) | [CLIA](#)
[CFR Title 21](#) | [Advisory Committees](#) | [Assembler](#) | [Recalls](#) | [Guidance](#) | [Standards](#)

[New Search](#)[Back To Search Results](#)

Device Classification Name	<u>Dressing, Wound, Drug</u>
510(K) Number	K071371
Device Name	COPA AMD ANTIMICROBIAL WOUND DRESSING
Applicant	TYCO HEALTHCARE GROUP, LP 15 Hampshire St. Mansfield, MA 02048
Contact	James Walsh
Classification Product Code	<u>FRO</u>
Date Received	05/16/2007
Decision Date	11/19/2007
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	General & Plastic Surgery
Review Advisory Committee	General & Plastic Surgery
Statement/Summary/Purged Status	Summary Only
Summary	<u>Summary</u>
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No

000141

2u7 7/27/2005

KENDALL

15 HAMPSHIRE STREET, MANSFIELD, MASSACHUSETTS 02048 • (508) 261-8000

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.

012

KENDALL

15 HAMPSHIRE STREET, MANSFIELD, MASSACHUSETTS 02048 • (508) 261-8000

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.

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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" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (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.

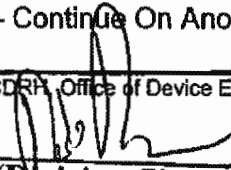
Prescription Use x
(Part 21 CFR 801 Subpart D)

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 CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

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

510(k) Number K071371

Page 1 of 1

[HOME](#) | [SITEMAP](#)[PRODUCTS](#) [HOW IT WORKS](#) [COST SAVING WITH AMD™](#)

PRODUCT INFORMATION

Covidien AMD™ Antimicrobial Dressings contain PHMB (polyhexamethylene biguanide), a bacteria-killing polymer. PHMB attacks bacteria on and within the dressing fabric, helping keep infection out of the wound and limiting cross-contamination.

Covidien AMD™ Antimicrobial Dressings treated with PHMB are used like standard dressings automatically comply with your facility's existing protocol.

Here's how PHMB works:

1. PHMB binds to bacteria's phospholipid (outer) membrane
2. Disrupts membrane, causing cytoplasm to leak out
3. Cell's protective layer disintegrates
4. Cell collapses and dies

** PHMB works similarly to dismantle gram-negative bacteria*

Effective against:

- Methicillin-resistant *Staphylococcus aureus* (MRSA)
- Vancomycin-resistant enterococcus (VRE)
- *Acinetobacter Baumannii* (MDRAB)
- *Staphylococcus aureus*
- *Staphylococcus epidermitis*
- *Pseudomonas aeruginosa*
- *Escherichia coli*
- *Candida albicans*
- *Staphylococcus coagulase*
- *Proteus mirabilis*
- *Serratia marcescens*
- *Enterobacter cloacae*
- *Klebsiella pneumoniae*
- *Enterococcus faecalis*

[Watch the video!](#)

See how PHMB destroys bacteria.

HOW TO Get Started!

Make Covidien AMD™
Antimicrobial Dressings part of
your infection control plan today.

[MORE >>](#)

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Appendix 1.2
Kerlix AMD
K990530
(Referenced in K071371 as a predicate)

PolyRemedy, Inc.
PolyFIT+ Absorbing Antimicrobial Dressings

Premarket Notification

510(k) Premarket Notification



[510\(k\)](#) | [Registration & Listing](#) | [Adverse Events](#) | [PMA](#) | [Classification](#) | [CLIA](#)
[CFR Title 21](#) | [Advisory Committees](#) | [Assembler](#) | [Recalls](#) | [Guidance](#) | [Standards](#)

[New Search](#)

[Back To Search Results](#)

Device Classification Name	<u>Dressing, Wound, Occlusive</u>
510(K) Number	K990530
Device Name	KERLIX MD ANTIMICROBIAL GAUZE DRESSING
Applicant	THE KENDALL COMPANY, L.P. 15 Hampshire St. Mansfield, MA 02048
Contact	David A Olson
Regulation Number	<u>878.4020</u>
Classification Product Code	<u>NAD</u>
Date Received	02/19/1999
Decision Date	01/31/2000
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	General & Plastic Surgery
Review Advisory Committee	General & Plastic Surgery
Statement/Summary/Purged Status	Summary/Purged 510(K)
Summary	<u>Summary</u>
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No

JAN 31 2000

EXHIBIT #12

K990530

510(k) Summary**Kendall Kerlix MD Antimicrobial Gauze Dressing**

In accordance with section 513(l) of the SMDA and as defined in 21 CFR Part 807.3 final rule dated December 14, 1994, this summary is submitted by:

The Kendall Company LP**15 Hampshire Street****Mansfield, MA 02048****Date Prepared: February 12, 1999****1. Contact Person**

David A. Olson
Director, Regulatory Affairs
(508) 261-8530

2. Name of Medical Device

Classification Name: Unclassified
Common or Usual Name: Kerlix MD Antimicrobial Gauze Dressing

3. Identification of Legally Marketed Device

The proposed Kendall Kerlix MD Antimicrobial Gauze Dressing is substantially equivalent in intended use, function and composition to Vitaphore Corporations Vitapatch, 510(k) No. K895993 and Maersk Medical Ltd. Arglaes Antimicrobial Barrier Film Dressing, 510(k) No. K973657.

4. Device Description

The proposed Kerlix MD Antimicrobial Gauze Dressing is a sterile, single use, wound dressing consisting of gauze treated with Polyhexamethylene Biguanide Hydrochloride. The dressing is packaged in Tyvek/Poly pouches as well as Tyvek/Styrene trays and is available in both sponge and roll form.

5. Device Intended Use

The Kendall Kerlix MD Antimicrobial Gauze Dressing is intended for use as a primary dressing for exuding wounds, first and second degree burns, as a cover for surgical wounds, to secure and prevent movement of primary dressings and as a wound packing.

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6. Product Comparison

The Kendall Kerlix MD Antimicrobial Gauze Dressing is equivalent to the referenced predicate devices in that they are intended to be used as wound coverings, they each contain an ingredient that enhances the bacterial barrier function of the dressing and each has a broad spectrum of antimicrobial activity.

7. Nonclinical Testing

Biocompatibility testing of the Kendall Kerlix MD Antimicrobial Gauze Dressing has demonstrated that it meets the requirements of guidelines presented in the 10993 ISO Standard, Part 1, with the FDA modified matrix presented in memorandum G95-1.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 31 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Frank J. Fucile, Esq.
Vice President, Regulatory Affairs
The Kendall Company, L.P.
15 Hampshire Street
Mansfield, Massachusetts 02048

Re: K990530
Trade Name: Kendall Kerlix™ Antimicrobial Gauze
Regulatory Class: I
Product Code: NAD
Dated: October 11, 1999
Received: November 3, 1999

Dear Mr. Fucile:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act). You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. This device may not be labeled for use on third degree burns.
2. This device may not be labeled as having any accelerating effect on the rate of wound healing or epithelization.
3. This device may not be labeled as a long-term, permanent, or no-change dressing, or as an artificial (synthetic) skin.
4. This device may not be labeled as a treatment or a cure for any type of wound.

The labeling claims listed above would be considered a major modification in the intended use of the device and would require a premarket notification submission (21 CFR 807.81).

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

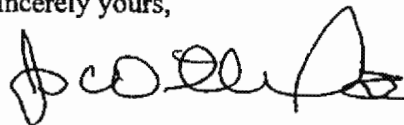
Page 2 - Mr. Frank J. Fucile, Esq.

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

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

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

Sincerely yours,



James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K990530

INDICATIONS FOR USE STATEMENT

510K Number: K990530

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

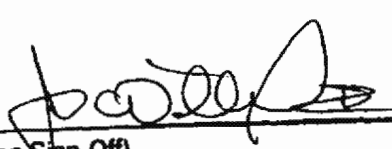
Indications for Use:

KERUX 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

Efficacy of AMD[™] Dressings Against MRSA and VRE

Chirag B. Shah, Ph.D. (Manager, Bioscience R&D, THC, Mansfield, MA)
Ellen Swogger and Garth James, Ph.D. (CBE, Montana State University, Bozeman, MT)

Efficacy of AMD™ Dressings Against MRSA and VRE

Chirag B. Shah, Ph.D. (Manager, Bioscience R&D, Kendall, Mansfield, MA)
Ellen Swogger and Garth James, Ph.D. (CBE, Montana State University, Bozeman, MT)

SUMMARY

Studies were performed to evaluate the efficacy of PHMB treated AMD dressings against *Methicillin Resistant Staphylococcus aureus* (MRSA), and also against *Vancomycin Resistant Enterococcus faecalis* (VRE), in preventing microbial growth on the dressings. *KERLIX*™ AMD, *CURITY*™ AMD and *EXCILON*™ AMD dressings containing 0.2% polyhexamethylene biguanide (PHMB) were directly inoculated with clinical isolates of MRSA or VRE and placed on growth mediums. The presence or absence of microbial growth was observed visually and under a Scanning Electron Microscope (SEM) for three days. All AMD dressings significantly inhibited growth of MRSA and VRE on and within dressings, as compared to untreated control dressings.

INTRODUCTION

Kendall AMD dressings contain 0.2% PHMB as a broad-spectrum antimicrobial agent [1]. *KERLIX* AMD and *CURITY* AMD dressings are cotton-based gauze dressings. *EXCILON* AMD dressings are rayon/polyester based drain sponge dressings. The PHMB in AMD dressings functions as an agent that reduces bacterial colonization within the dressing and bacterial penetration through the dressing.

The effectiveness of *KERLIX* AMD dressings as a barrier to bacterial penetration has been demonstrated in animal models as well as in a human clinical case series [2-4]. It has also been demonstrated that packing wounds with *KERLIX* AMD gauze dressings may be beneficial in reducing the bacterial bioburden in terms of both the total amount of microorganisms and the number of species [4]. In one prospective, randomized controlled

open-label clinical case series, it was determined that *EXCILON* AMD drain sponge dressings could be an important adjunct in the control of antibiotic-resistant bacterial infection as well as other infections frequently found in patients with tracheostomies. The study results suggested that *EXCILON* AMD dressings can help control organisms such as MRSA and *P. aeruginosa* in an institutional setting [5].

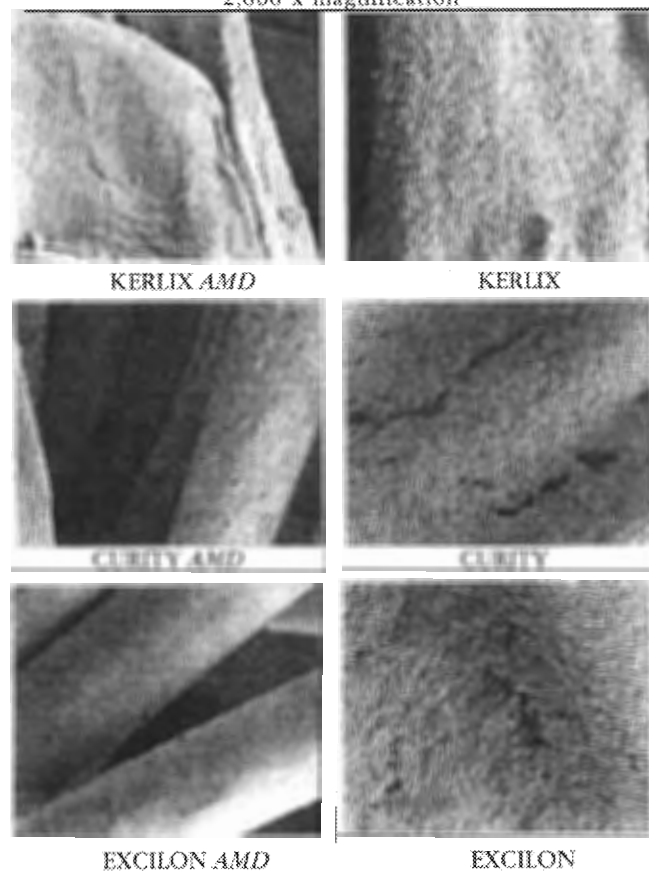
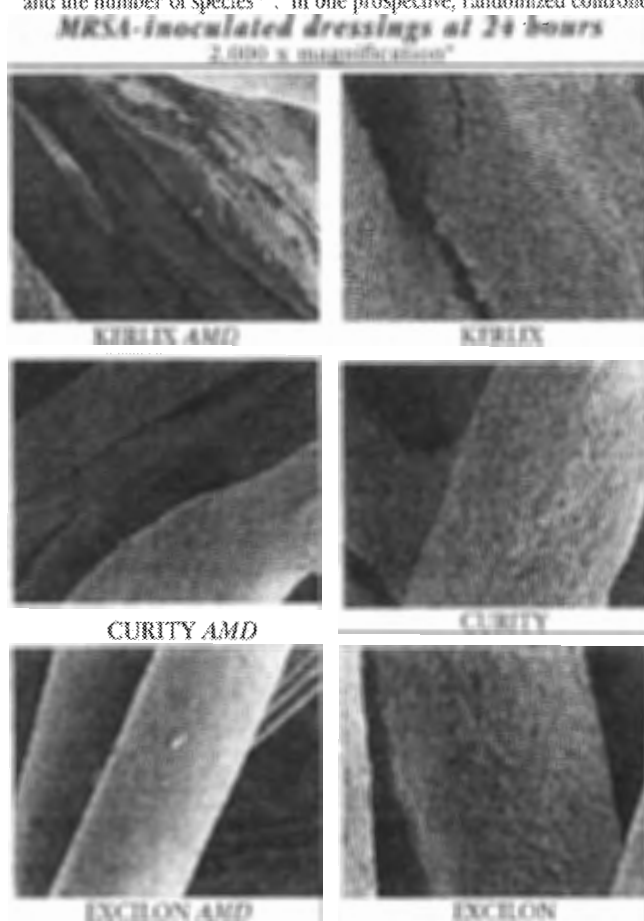
Broad-spectrum activity of AMD dressings against gram positive and gram negative bacteria as well as fungi has been demonstrated in several *in vitro* studies [6-9]. In one study, *KERLIX* AMD dressings visually exhibited a very high degree of antimicrobial efficacy and reduced growth of MRSA and VRE at 24 and 48 hours following direct inoculation on the dressing at 10⁶ cfu/mL challenge level [8-9]. In another study, *KERLIX* AMD dressings exhibited high antimicrobial activity by 3-6 log reduction of MRSA challenge and 4-5 log reduction of VRE challenge at 30 minutes and 2 hours post inoculation of the dressing [10].

The purpose of this paper is to illustrate efficacy of three types of AMD dressings against clinical isolates of MRSA and VRE in preventing microbial growth on and within the dressings. The test dressings were directly inoculated with a suspension of MRSA or VRE and observed visually and under SEM for the growth/no growth on the dressings.

MATERIALS

Test Articles		Controls	
<i>KERLIX</i> AMD	Lot# 51172700	<i>KERLIX</i>	Lot# 51532606
<i>CURITY</i> AMD	Lot# 51056501	<i>CURITY</i>	Lot# 51337800
<i>EXCILON</i> AMD	Lot# 51448601	<i>EXCILON</i>	Lot# 50977500

MRSA-inoculated dressings at 72 hours 2,000 x magnification*



*Enlarged for clarity

Challenge Organisms

The methicillin-resistant *Staphylococcus aureus* (MRSA) strain used in this study was obtained from Dr. Mark Shirliff, Dept. of Microbiology and Immunology, School of Medicine, University of Maryland-Baltimore. It was originally isolated from a bone debridement sample from a patient undergoing treatment for osteomyelitis at the University of Texas Medical Branch.

The Vancomycin-resistant *Enterococcus* (VRE) *faecalis* strain used in this study was obtained from the American Type Culture Collection (ATCC 700802). This strain was originally isolated from a human blood sample.

METHODS

Inoculation and Bacterial Growth

MRSA and VRE cultures were each grown in Tryptic Soy Broth (TSB) at 37°C for 24 h. They were then diluted 1:10 with fresh TSB prior to inoculation of the dressing samples. The approximate cell density of the MRSA culture was 1×10^8 cfu/mL. The approximate cell density of the VRE culture was 6×10^8 cfu/mL.

The dressing samples were first cut into 20mm, 1-ply squares and then inoculated by holding them with sterile forceps and dipping into the diluted cultures. After inoculation, the dressings were immediately placed onto Trypticase Soy Agar (TSA) plates, and incubated at 37°C. They were transferred to fresh TSA every 24 hours.

Scanning Electron Microscopy

After 2 days incubation, the dressing samples were removed from the TSA plates and placed in a sterile Petri dish. Each dressing was treated with one mL of 50% ethanol for 10 minutes, after which the ethanol was decanted. This procedure was repeated with 70% and 100% ethanol to dehydrate the samples for SEM. Following dehydration, the samples were sputter coated

with 10 nm layer of gold-palladium and imaged on a JEOL model 6100 Scanning Electron Microscope, which uses a LaB6 electron source. The acceleration voltage was set to 10kV with a working distance of 8mm.

RESULTS

Efficacy of AMD dressings

Antimicrobial efficacy of *KERLIX* AMD, *CURITY* AMD, and *EXCILON* AMD dressings against MRSA and VRE is illustrated in the following SEM pictures at 2,000 times magnification levels [enlarged 200% in this literature]. These images were collected after 24 hours and again at 72 hours. It can be observed that AMD dressings significantly inhibited growth of MRSA and VRE on and within the dressings, compared to untreated *KERLIX*, *CURITY* and *EXCILON* dressings.

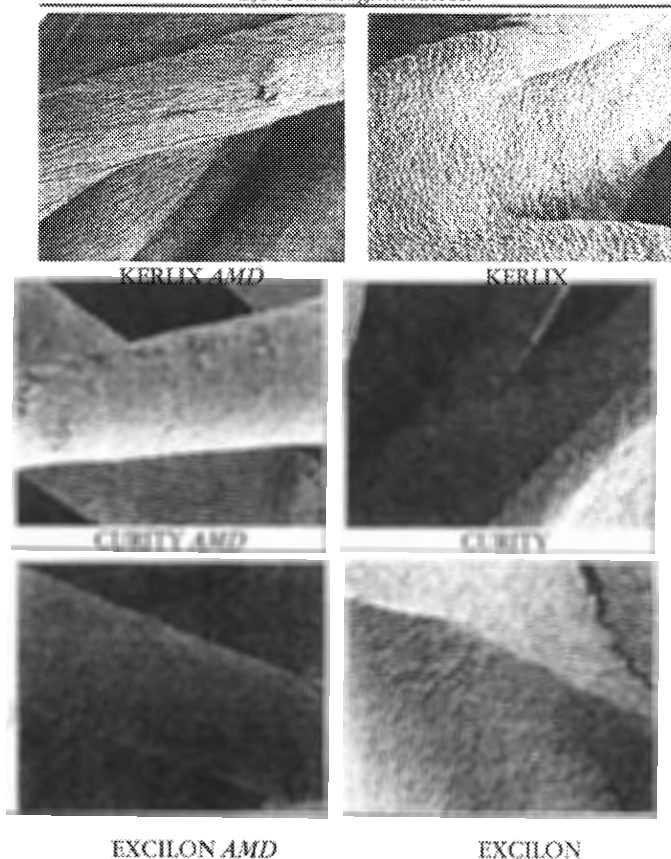
DISCUSSION

The studies reported in this paper involved direct inoculation of the test materials in which results are reported on a visual scale. The presence or absence of activity is a good indication of the efficacy of a test sample. All AMD dressings exhibited excellent ability to inhibit growth on and within the dressing compared to control dressings. The significance of these observations is that the contaminated traditional wound dressings could provide support for microbes to grow unchallenged and might lead to increase in bioburden in the wound. However, the use of antimicrobial dressings could prevent or reduce growth of the microbes that contact the dressings via exogenous contamination or absorption of wound exudates.

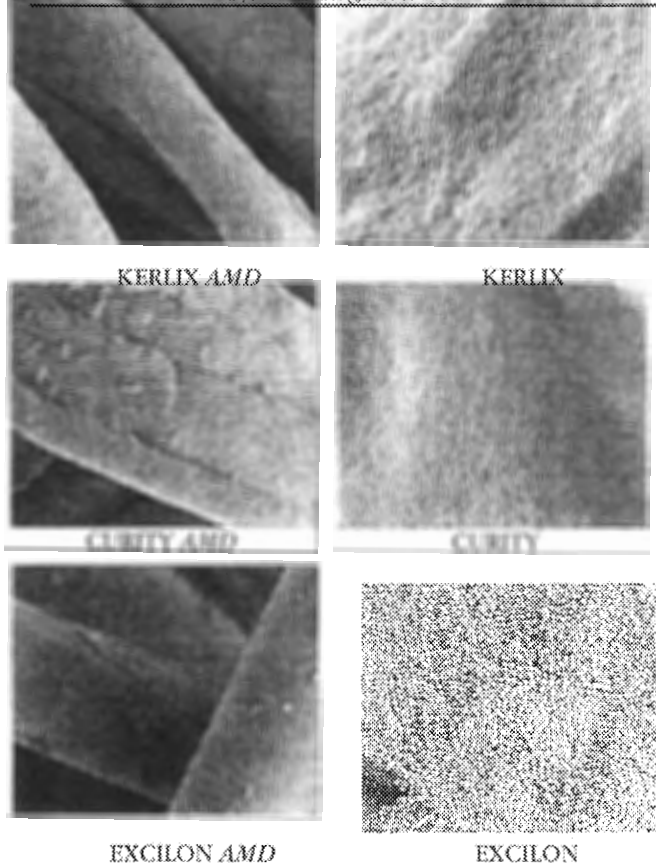
CONCLUSION

PHMB treated AMD dressings (i.e. *KERLIX* AMD, *CURITY* AMD and *EXCILON* AMD) exhibit antimicrobial activity against MRSA and VRE in terms of resisting bacterial colonization within the dressing and inhibit bacterial penetration through the dressing for up to 72 hours.

VRE-inoculated dressings at 24 hours
2,000 x magnification*



VRE-inoculated dressings at 72 hours
2,000 x magnification*



*Enlarged for clarity

REFERENCES

1. Intrinsic activity of Casimodil CQ - Technical brief on PHMB, Avecia Biocides Inc.
2. Patricia Mertz et al. "The Effect of an Antimicrobial Gauze Dressing Impregnated with 0.2% Polyhexamethylene Biguanide (PHMB) as a Barrier to prevent *Pseudomonas aeruginosa* Wound Invasion", 9-01.
3. Angeliqne M. Reisma, M.D. and George T. Rodcheaver, Ph.D., "Effectiveness of a New Antimicrobial Gauze Dressing as a Bacterial Barrier", 6-01
4. Glenda J. Motta, RN et al. "Impact of an Antimicrobial Gauze upon Bacterial Colonies in Wounds that Require Packing", 5-03
5. Glenda J. Motta, RN and Donna Triglia, APRN. "Impact of an Antimicrobial Drain Sponge Dressing Upon Specific Bacterial Isolates at Tracheostomy Sites", 5-03.
6. William R. Lee et al. "In Vitro efficacy of Polyhexamethylene Biguanide Impregnated Gauze Dressings against Bacteria Found in Veterinary Patients", *Veterinary Surgery*, 33:404-411, 2004.
7. TDC Technical studies-dam on file
8. Jamie M. Case, "Microbial Challenge Test for Porous Materials Using Vancomycin Resistant *Enterococcus faecalis*", 9-01.
9. Jamie M. Case, "Microbial Challenge Test for Porous Materials Using Methicillin Resistant *Staphylococcus aureus*", 9-01.
10. Carrie L. Gillant-Belun et al. "Comparison of In-Vitro Disc Diffusion and Time Kill-Kinetic Assays for the Evaluation of Antimicrobial Wound Dressing Efficacy", *Wound Rep Reg* 2005; 13: 412-421.

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**The Effect of an
Antimicrobial Gauze Dressing
Impregnated with
0.2% Polyhexamethylene Biguanide
(PHMB)
as a Barrier to Prevent
Pseudomonas aeruginosa
Wound Invasion**

Patricia Mertz, Alejandro Cazzaniga, Victoria Serralta,
Stephen Davis, Robert Orr*, and William Eaglstein,
University of Miami, Department of Dermatology and Cutaneous Surgery,
University of Miami School of Medicine, Miami, Florida,
*Kendall, Wound Care Research and Development, Mansfield, MA

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POLYFIT™+ ABSORBING ANTIMICROBIAL DRESSING 510(K) PREMARKET NOTIFICATION

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PolyRemedy, Inc.
PolyFIT + Absorbing Antimicrobial Dressings

Premarket Notification

20. Performance Testing- Animals

This section does not apply.

PolyRemedy, Inc.
PolyFIT+ Absorbing Antimicrobial Dressings

Premarket Notification



COVER SHEET MEMORANDUM

From: Reviewer Name
Subject: 510(k) Number
To: The Record

Gene L. Mathew
1092351/S1

Please list CTS decision code SE

- ☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- ☐ Hold (Additional Information or Telephone Hold).
- ☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	☒	☐
510(k) Summary <u>510(k) Statement</u>	Attach Summary	☒	☐
Truthful and Accurate Statement.	Must be present for a Final Decision	☒	☐
Is the device Class III?		☐	☒
If yes, does firm include Class III Summary?	Must be present for a Final Decision	☒	☐
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		☒	☒
Is this a combination product? (Please specify category <u>N</u> see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)		☒	☐
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)		☐	☒
Is this device intended for pediatric use only?		☒	☐
Is this a prescription device? (If both prescription & OTC, check both boxes.)		☒	☐
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		☒	☐
Is clinical data necessary to support the review of this 510(k)?		☐	☒
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)		☐	☒
Does this device include an Animal Tissue Source?		☐	☒
All Pediatric Patients age ≤ 21		☐	☒
Neonate/Newborn (Birth to 28 days)		☐	☒
Infant (29 days - < 2 years old)		☐	☒
Child (2 years - < 12 years old)		☐	☒
Adolescent (12 years - < 18 years old)		☐	☒
Transitional Adolescent A (18 - < 21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)		☐	☒

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)		✓
Nanotechnology		✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)		Contact OC.

Regulation Number	Class*	Product Code
	<i>Unclassified</i>	<i>P20</i>
(If unclassified, see 510(k) Staff)		

Additional Product Codes:

Review:	<i>David Krone</i>	<i>PRSB</i>	<i>April 8, 2010</i>
	(Branch Chief)	(Branch Code)	(Date)
Final Review:	<i>Mark A. Williams</i>		<i>4/8/10</i>
	(Division Director)		(Date)



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

October 22, 2009

POLYREMEDY, INC.
24372 MCCLOUD COURT
LAGUNA NIGUEL, CALIFORNIA 92677
UNITED STATES
ATTN: GARY MOCNIK

510k Number: K092351

Product: POLY FIT + ABSORBING AND HIGH

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission **MUST** cite your 510(k) number and be sent in duplicate to the Document Mail Center 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

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>.

The deficiencies identified 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/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm>.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). 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". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

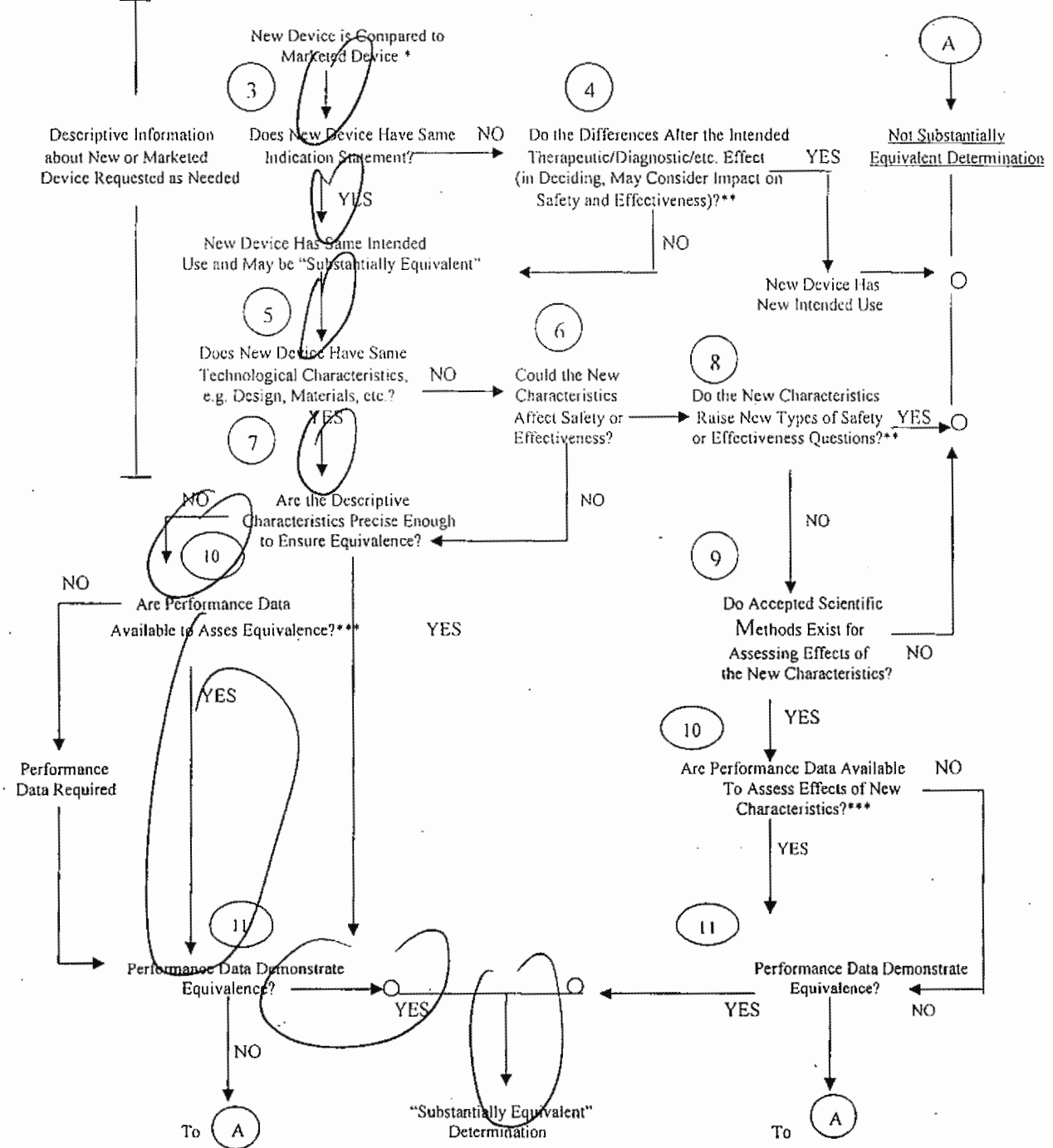
- Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

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

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.

16. Biocompatibility

Applied Standard

ISO 10993 was used as a standard for biocompatibility compliance. ISO 10993-1 was used to determine the appropriate categorization of the device based on the nature and duration of contact with the body. The Blue Book Memorandum G95-1 entitled "Use of International Standard ISO- 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" and Table 1 of ISO 10993-1 were used as tools for the initial evaluation of tests for consideration.

Categorization of the device

Intended Use

PolyFIT+ Absorbing Antimicrobial Dressings are intended as effective barriers to inhibit microbial proliferation within the dressing and reduce microbial penetration through the dressing. PolyFIT+ Absorbing Antimicrobial Dressings are for use under a healthcare professional's orders as adjunctive treatment in the management of exudating wounds, partial and full-thickness wounds, such as pressure ulcers (Stages II-IV), lower extremity ulcers (venous or arterial), diabetic foot ulcers, surgical or traumatic wounds (including those left open to heal by secondary intention). They are not intended for wounds with exposed tendon or bone, for 3rd degree burns or for dry wounds.

Nature and duration of body contact

PolyFIT+ Absorbing Antimicrobial Dressings are designed to be used on breached skin surface wounds for a 7 day period or less.

Device Categorization

PolyFIT+ Absorbing Antimicrobial Dressings are considered a prolonged (< 30 days) contacting device with breached or compromised surfaces device.

PolyRemedy, Inc.
PolyFIT + Absorbing Antimicrobial Dressings

Premarket Notification

Test Selection

Based on the device categorization outlined above, the nature of the material contact and the guidance given in ISO 10993-1 as well as FDA Blue Book memorandum G-95, tests for the device materials were selected as shown in the table below:

Table : Materials List/Test Selection

(b)(4)

Tests for Sub-Acute/Sub-Chronic Systemic and Implantation

(b)(4)

PolyRemedy, Inc.
PolyFIT + Absorbing Antimicrobial Dressings

Premarket Notification

(b)(4)

Toxicity Profile- PHMB

(b)(4)

PolyRemedy, Inc.
PolyFIT + Absorbing Antimicrobial Dressings

Premarket Notification

(b)(4)

Results

All studies were performed at an independent laboratory. All test samples were representative of finished devices and included the antimicrobial agent. The biocompatibility test report matrix below summarizes the results of the tests performed.

Table: Biocompatibility Test Results Summary

(b)(4)

(b)(4)

Conclusion

The PolyFIT+ Absorbing Antimicrobial Dressing passed each test as outlined. The results from all tests indicate that PolyFIT+ Absorbing Antimicrobial Dressings are non-toxic, non-irritating and non-sensitizing and, therefore, biocompatible for their intended use.

PolyRemedy, Inc.
PolyFIT + Absorbing Antimicrobial Dressings

Premarket Notification

K092351

510(k) PREMARKET NOTIFICATION

PolyFIT™ + Absorbing Antimicrobial Dressings

FDA CDRH DMC

AUG 04 2009

Received

APPLICANT

PolyRemedy, Inc.
2637 Marine Way, # 100
Mountain View, CA 94043

OFFICIAL CORRESPONDENT

Gary Mocnik

Phone: (b)(6)

Email: garym@PolyRemedy.com



COVER SHEET MEMORANDUM

From: Reviewer Name

Subject: 510(k) Number

To: The Record

Please list CTS decision code

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist
http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☒ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU		
510(k) Summary /510(k) Statement	Attach Summary		
Truthful and Accurate Statement.	Must be present for a Final Decision		
Is the device Class III?			
If yes, does firm include Class III Summary?	Must be present for a Final Decision		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age <=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 -<21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			

Transitional Adolescent B (18 <= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)		Contact OC.	
Regulation Number	Class*	Product Code	

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

Additional Product Codes:

Review: David Krue APSB Oct. 20, 2009
 (Branch Chief) (Branch Code) (Date)

Final Review: David Krue 10/20/2009
 (Division Director) (Date)

Ngatha, George

From: Ngatha, George
Sent: Tuesday, October 20, 2009 12:36 PM
To: 'Gary Mocnik'
Cc: Krause, David
Subject: K092351 (b)(4) Poly Fit Absorbing & Hydrating Antimicrobial Wound dressings

Attachments: (b)(4) K092351.AI-Poly Fit Absorbing & High Absorbing.doc

(b)(4)



K092351.AI-Poly Fit
Absorbing ...

Dear Mr.Mocnik:

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 additional information (see attached AI letters).

If you have any questions concerning the contents of the letter, please contact me at the number listed below.

Sincerely,
George K. Ngatha ChE.Eng
LTJG, U.S. Public Health Service
FDA Center for Devices and Radiological Health
Office of Device Evaluation
Division of Surgical, Orthopedic Restorative Devices (DSORD)
W066 Room # 3625
10903 New Hampshire Ave
Silver Spring, MD 20993
Phone: 301-796-5650
E-mail: George.Ngatha@fda.hhs.gov

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. IF YOU ARE NOT THE INTENDED RECIPIENT, YOU ARE HEREBY NOTIFIED THAT ANY DISCLOSURE, DISSEMINATION, DISTRIBUTION, COPYING, OR OTHER ACTION BASED ON THE CONTENT OF THIS COMMUNICATION IS NOT AUTHORIZED. IF YOU HAVE RECEIVED THIS DOCUMENT IN ERROR, PLEASE IMMEDIATELY NOTIFY George K. Ngatha by email at George.Ngatha@fda.hhs.gov or telephone at 301-796-5650.

Polymedo, Inc
C/o Gary Mocnik
24372 McCloud Ct.
Laguna Niguel, CA 92677
USA

Re: K092351

Trade Name: Poly Fit + Absorbing & High Absorbing Antimicrobial Dressings

Dated: August 2, 2009

Received: August 4, 2009

Dear Mr.Mocnik:

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 additional information to address the following items:

(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 (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

Page 2 – Mr. Gary Mocnik

the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the document titled “A Suggested Approach to Resolving Least Burdensome Issues” located at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073701.htm>

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 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 (21 CFR 812).

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k) (21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, “Guidance for Industry and FDA Staff: Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements” at www.fda.gov/cdrh/ode/guidance/1655.html.

If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm>.

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:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning the contents of the letter, please contact George K. Ngatha at (301) 796-6970. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer

Page 3 – Mr. Gary Mocnik

Assistance at its toll-free number (800) 638-2041 or at (301) 796-7100, or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

David Krause, Ph.D.
Chief, Plastic and Reconstructive
Surgery Branch
Division of Surgical, Orthopedic and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Page 4 – Mr.Gary Mocnik

Div/Branch	Last Name	Date	Div/Branch	Last Name	Date

Page 5 – Mr. Gary Mocnik



DEPARTMENT OF HEALTH AND HUMAN SERVICES

M E M O R A N D U M

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

**Premarket Notification [510(k)] Review
Traditional/Abbreviated**

(b)(5)

Date: 10/16/09

To: The Record

From: LTJG George K. Ngatha

Office: CDRH-ODE

Division: DSORD

510(k) Holder: Polymedo Inc.

Device Name: PolyFit Absorbing Antimicrobial Dressings and
PolyFit High Absorbing Antimicrobial Dressings

Contact: Gary Mocnick

Phone: **(b)(6)**

Fax: None

Email: garym@PolyRemedy.com

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

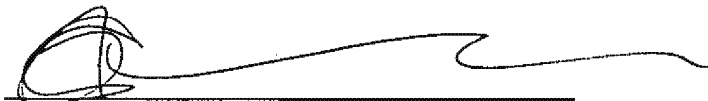
(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)



Reviewer

David Krone

Branch Chief

Date

10/19/2009

Date

I concur



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

APR - 8 2010

Poly Remedy, Inc.
% Mr. Gary Mocnik
2637 Marine Way, Suite 100
Mountain View, California 94043

Re: K092351

Trade/Device Name: PolyFIT™ + Absorbing Antimicrobial Dressings and
PolyFIT™ + High Absorbing Antimicrobial Dressings

Regulatory Class: Unclassified

Product Code: FRO

Dated: March 26, 2010

Received: March 29, 2010

Dear Mr. Mocnik:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

Page 2 - Mr. Gary Mocnik

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.

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

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



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

Enclosure

17. Software

This section does not apply.

PolyRemedy, Inc.
PolyFIT + Absorbing Antimicrobial Dressings

Premarket Notification

12. Device Description

(b)(4)

(b)(4)

(b)(4)

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(b)(4)

(b)(4)

(b)(4)

(b)(4)

Attachment 12.1

(b)(4) Information

(b)(4)

(b)(4)

Technical Information

(b)(4)

(b)(4)

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19. Performance Testing

The performance characteristics of the PolyFIT+ Absorbing Antimicrobial Dressings and the PolyFIT+ High Absorbing Antimicrobial Dressings were evaluated to demonstrate the safety and efficacy of the device for its intended use, and demonstrate substantial equivalence to the predicate devices.

The testing and analysis of the PolyFIT+ Absorbing Antimicrobial Dressings were based on the Risk Analysis and applicable requirements outlined in the draft FDA Guidance document "Premarket Notification (510k) Submissions for Medical Devices that Include Antimicrobial Agents", July 19, 2007. All test units were built simulating actual production conditions and were representative of finished devices. A summary table of the testing performed is found at the end of this section.

Wound Dressing Performance

A comparative test series was performed to assess the antimicrobial agent's affect on the established performance characteristics of the PolyFIT Absorbing and High Absorbing Wound Dressings.

Free Swell Absorptive Capacity Test ((b)(4) attached)

The Free Swell Absorptive Capacity test was used (b)(4)

(b)(4)

(b)(4)

The test protocol was based on the requirements outlined in DIN EN 13726-1, Test Methods for primary Wound dressings, (b)(4)

Materials and Methods

(b)(4)

Acceptance criteria

(b)(4)

Results

(b)(4)

Conclusion

(b)(4)

PolyRemedy, Inc.
PolyFIT+ Absorbing Antimicrobial Dressings

Premarket Notification

(b)(4)

Antimicrobial Agent Performance (b)(4) attached)

The antimicrobial effectiveness of the PolyFIT+ Absorbing Antimicrobial Dressing was challenged in a series of antimicrobial tests. All test units were representative of finished devices and in their final sterile form.

AATCC Test Method (b)(4) - Kill Rate Test

(b)(4)

PolyRemedy, Inc.
PolyFIT+ Absorbing Antimicrobial Dressings

Premarket Notification

(b)(4)

AATCC Test Method (b)(4)

(b)(4)

Microbial Barrier Strike-Through Test

(b)(4)

PolyRemedy, Inc.
PolyFIT+ Absorbing Antimicrobial Dressings

Premarket Notification

(b)(4)

AATCC Test Method (b)(4) - Sustained Antimicrobial Kill Rate Test in the Presence of Serum

(b)(4)

PolyRemedy, Inc.
PolyFIT+ Absorbing Antimicrobial Dressings

Premarket Notification

(b)(4)

PolyRemedy, Inc.
PolyFIT+ Absorbing Antimicrobial Dressings

Premarket Notification

Summary Table of Testing Performed

Test	Purpose	Test samples	Results
Free Swell Absorptive Capacity Test	(b)(4)	(b)(4)	(b)(4)
AATCC Test Method (b)(4) Kill Rate Test			
AATCC Test Method (b)(4)			
Microbial Barrier Strike-Through Test			

PolyRemedy, Inc.
PolyFIT+ Absorbing Antimicrobial Dressings

Premarket Notification

Test	Purpose	Test samples	Results
AATCC Test Method (b)(4) Sustained Antimicrobial Kill Rate Test in the Presence of Serum	(b)(4)		

PolyRemedy, Inc.
PolyFIT+ Absorbing Antimicrobial Dressings

Premarket Notification

Attachment 19.1

(b)(4)

PolyRemedy, Inc.
PolyFIT+ Absorbing Antimicrobial Dressings

Premarket Notification



Records processed under FOIA Request 2024-4348; Released by CDRH on 10-08-2024

DOCUMENT NUMBER:

(b)(4)

DOCUMENT TYPE: DESIGN REPORT

REV: (b)(4)

ABSORBENCY TESTING OF POLYFIT WOUND DRESSINGS WITH PHMB

(b)(4)

(b)(4)

Confidential Information

PAGE 1 OF 8

(b)(4)

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Attachment 19.2

(b)(4)

PolyRemedy, Inc.
PolyFIT+ Absorbing Antimicrobial Dressings

Premarket Notification



DOCUMENT NUMBER: (b)(4)

Reports processed under 21 CFR 312.63

DOCUMENT TYPE: DESIGN REPORT

CDRH on 10-08-2024

REV: (b)(4)

POLYFIT™+ ABSORBING ANTIMICROBIAL TEST REPORT

(b)(4)

(b)(4)

PolyRemedy Confidential

PAGE 1 OF 12

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

November 23, 2009

POLYREMEDY, INC.
24372 MCCLOUD COURT
LAGUNA NIGUEL, CALIFORNIA 92677
UNITED STATES
ATTN: GARY MOCNIK

510k Number: K092351

Product: POLY FIT + ABSORBING AND HIGH

Extended Until: 04/16/2010

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

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

7. Truthful and Accurate Statement

Pursuant to 21 CFR 807.87(j) I certify that in my capacity as President and Chief Executive Officer of PolyRemedy, 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 fact has been omitted.

(b)(6)

Daniel Eckert
President and CEO

7-30-09
Date

PolyRemedy, Inc.

PolyRemedy, Inc.
PolyFIT + Absorbing Antimicrobial Dressings

Premarket Notification

5. Indications for Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: **PolyFIT™+ Absorbing Antimicrobial Dressings and PolyFIT™+ High Absorbing Antimicrobial Dressings**

Indications for Use:

PolyFIT+ Absorbing Antimicrobial Dressings are intended as effective barriers to inhibit microbial proliferation within the dressing and reduce microbial penetration through the dressing. PolyFIT+ Absorbing Antimicrobial Dressings are for use under a healthcare professional's orders as adjunctive treatment in the management of exudating wounds, partial and full-thickness wounds, such as pressure ulcers (Stages II-IV), lower extremity ulcers (venous or arterial), diabetic foot ulcers, surgical or traumatic wounds (including those left open to heal by secondary intention). They are not intended for wounds with exposed tendon or bone, for 3rd degree burns or for dry wounds.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

OR

Prescription Use X
(Per 21 CFR 801.109)Over-The-Counter Use _____
(Optional Format 1-2-96)

Page __ of __

PolyRemedy, Inc.
PolyFIT + Absorbing Antimicrobial Dressings

Premarket Notification

4. Cover Letter

(See attached)

PolyRemedy, Inc.
PolyFIT + Absorbing Antimicrobial Dressings

Premarket Notification

July 31, 2009

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

RE: 510(k) Notification - Traditional

To whom it may concern:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act ("FDC Act"), this letter is provided to notify the Food and Drug Administration "FDA" or the "agency" of the intention of PolyRemedy, Inc., to manufacture and market PolyFIT™ + Absorbing Antimicrobial Dressings and PolyFIT™ + High Absorbing Antimicrobial Dressings. PolyRemedy believes the appropriate classification of the device to be Unclassified (preamendment), Dressing, Wound, Drug: Product Code FRO.

PolyRemedy is submitting this Traditional 510(k) Notification in accordance with 21 CFR 807, Subpart E. Two (2) copies of this submission are included with this correspondence.

The design and use of the PolyFIT+ Absorbing Antimicrobial Dressings are presented below in tabular form:

Question	Yes	No
Is the device intended for prescription use?	X	
Is the device intended for over-the-counter use?		X
Does the device contain components from a tissue or biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
Does the device contain a drug?	X	
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

PolyRemedy, Inc.
PolyFIT + Absorbing Antimicrobial Dressings

Premarket Notification

The existence of this Premarket Notification and the data and other information that it contains are confidential, and the protection afforded to such confidential information by 21 CFR 807.95, and other applicable laws is hereby claimed.

All questions and/or comments concerning this submission should be made to:

Gary Mocnik
24372 McCloud Court, Laguna Niguel, CA 92677
Phone: (b)(6)
Email: garym@PolyRemedy.com

Sincerely,

(b)(6)

Daniel Eckert
President and CEO
PolyRemedy, Inc.
650.960.2404 x111
dan@polyremedy.com

PolyRemedy, Inc.
PolyFIT + Absorbing Antimicrobial Dressings

Premarket Notification



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

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

**Premarket Notification [510(k)] Review
Traditional/Abbreviated**

(b)(5)

K092351.S1

Date: 4/06/10

To: The Record

From: LTJG George K.Ngatha

Office: CDRH-ODE

Division: DSORD

510(k) Holder: Polymedo Inc.

Device Name: PolyFit Absorbing Antimicrobial Dressings and
PolyFit High Absorbing Antimicrobial Dressings

Contact: Gary Mocnick

Phone: (b)(6)

Fax: None

Email: garym@PolyRemedy.com

I. Purpose and Submission Summary

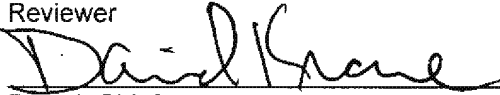
(b)(5)

(b)(5)

(b)(5)

(b)(5)



Reviewer


Branch Chief

4/8/10

Date
4/8/2010

Date





Premarket Notification 510(k) Statement

(As Required By 21 CFR 807.93)

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

(b)(6)

Gary Mocnik

April 7, 2010

Premarket Notification [510(k)] Number: K092351

Ngatha, George

From: Gary Mocnik [garym@polyremedy.com]
Sent: Wednesday, April 07, 2010 4:25 PM
To: Ngatha, George
Subject: RE: K092351.S1& (b)(4)
Attachments: (b)(4) statement k092351 4-7-10.pdf

George,
As we discussed this morning, attached are 510k statements for the above referenced submissions.
Call me with any comments or if you need any additional information

Gary

(b)(6)

From: Ngatha, George [mailto:George.Ngatha@fda.hhs.gov]
Sent: Wed 4/7/2010 10:15 AM
To: Gary Mocnik
Subject: RE: K092351.S1& (b)(4)

Gary-

I looked at your draft,

(b)(4)

(b)(4)

Please make the necessary corrections and email me the final version .I will not be able to get to it before tomorrow (leaving at 3PMEST).Should there be any questions, I will contact you tomorrow morning (EST)

Thanks,
George.

From: Gary Mocnik [mailto:garym@polyremedy.com]
Sent: Tuesday, April 06, 2010 7:47 PM
To: Ngatha, George
Subject: RE: K092351.S1& (b)(4)

George,
Thanks for the call yesterday. attached is a draft based on your email and our conversation. Please let me know if this is sufficient or comment on any additional requirements. I will then revise the other submission and formally submit both to you.

Thanks in advance

Gary Mocnik

(b)(6)

From: Ngatha, George [mailto:George.Ngatha@fda.hhs.gov]**Sent:** Tue 4/6/2010 1:10 PM**To:** Gary Mocnik**Subject:** K092351.S1 (b)(4)

Gary, <<510kSummary Checklist.doc>>

(b)(4)

See attached checklist for more details.

Thanks,

George.

George K. Ngatha ChE. Eng.

LTJG, U.S. Public Health Service

FDA/ODE/DAGID

WO66 Room # 3625

10903 New Hampshire Ave

Silver Spring, MD 20993

Phone: 301-796-5650

Fax: 301-847-8188

E-mail: George.Ngatha@fda.hhs.gov

Section 1

Medical Device User Fee Cover Sheet

1. Medical Device User Fee Cover Sheet (Form FDA 3601)

(See attached)

PolyRemedy, Inc.
PolyFIT + Absorbing Antimicrobial Dressings

Premarket Notification

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.	
Completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html			
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) POLYREMEDY INC 2637 MARINE WAY SUITE 100 MOUNTAIN VIEW CA 94043 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) 201772086		2. CONTACT NAME Gary Mocnik 2.1 E-MAIL ADDRESS garym@polyremedy.com 2.2 TELEPHONE NUMBER (include Area code) (b)(6) 2.3 FACSIMILE (FAX) NUMBER (Include Area code)	
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma) Select an application type: ☒ Premarket notification(510(k)); except for third party ☐ 513(g) Request for Information ☐ Biologics License Application (BLA) ☐ Premarket Approval Application (PMA) ☐ Modular PMA ☐ Product Development Protocol (PDP) ☐ Premarket Report (PMR) ☐ Annual Fee for Periodic Reporting (APR) ☐ Lay Notice 3.1 Select a center ☒ CDRH ☐ CBER 3.2 Select one of the types below ☒ Original Application Supplement Types: ☐ Efficacy (BLA) ☐ Panel Track (PMA, PMR, PDP) ☐ Real-Time (PMA, PMR, PDP) ☐ 180-day (PMA, PMR, PDP)			
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) ☒ YES, I meet the small business criteria and have submitted the required qualifying documents to FDA ☐ NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number: SBD096085			
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? ☐ YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) ☐ NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)			
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. ☐ This application is the first PMA submitted by a qualified small business, including any affiliates ☐ This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only ☐ The sole purpose of the application is to support conditions of use for a pediatric population ☐ The application is submitted by a state or federal government entity for a device that is not to be distributed commercially			
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).) ☐ YES ☒ NO			
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b)(4)		19-Jun-2009	

FDA 3601 (01/2007)

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

000002

107

7/28/2009

11. Executive Summary

(b)(4)

PolyRemedy, Inc.
PolyFIT + Absorbing Antimicrobial Dressings

Premarket Notification

(b)(4)

(b)(4)

Section 3

Standards Data Report Form(s)

~~Records processed under FOIA Request 2024-4348; Released by CDRH on 10-06-2024~~

3. Standards Data Report FDA Form 3654

(See attached)

PolyRemedy, Inc.
PolyFIT + Absorbing Antimicrobial Dressings

Premarket Notification

Records processed under FOIA Request 2024-4348; Released by CDRH on 10-08-2024
 Department of Health and Human Services
 Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE ¹

ISO 11607-1: 2006 Packaging for terminally sterilized medical devices- Part 1: Requirements for materials, sterile barrier systems

Please answer the following questions

Yes No

Is this standard recognized by FDA ²? ☒ ☐

FDA Recognition number ³ # 14-193

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? ☒ ☐

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? ☐ ☒
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? ☒ ☐

Does this standard include acceptance criteria? ☒ ☐
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? ☒ ☐
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? ☐ ☒
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵? ☐ ☐

Were deviations or adaptations made beyond what is specified in the FDA SIS? ☐ ☒
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? ☐ ☒
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard? ☐ ☒
 If yes, was the guidance document followed in preparation of this 510(k)? ☐ ☐

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier]
 [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE

SUMMARY REPORT TABLE

STANDARD TITLE

ISO 11137-1: 2006 Sterilization of Health Care Products- Radiation- Part 1: Requirements for development of validation

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	All	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
(b)(4)		
DESCRIPTION		
(b)(4)		
JUSTIFICATION		
(b)(4)		
SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.		
* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.		

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and 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:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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Department of Health and Human Services
Food and Drug Administration

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(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE¹

ISO 11137-1: 2006 Sterilization of Health Care Products- Radiation- Part 1 Requirements for development of validation

Please answer the following questions

Yes No

Is this standard recognized by FDA²? ☒ ☐

FDA Recognition number³ # 14-224

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? ☒ ☐

Is a summary report⁴ describing the extent of conformance of the standard used included in the 510(k)? ☐ ☒
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? ☒ ☐

Does this standard include acceptance criteria? ☒ ☐
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? ☒ ☐
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? ☐ ☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵? ☐ ☐

Were deviations or adaptations made beyond what is specified in the FDA SIS? ☐ ☒
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? ☐ ☒
If yes, report these exclusions in the summary report table.

Is there an FDA guidance⁶ that is associated with this standard? ☒ ☐
If yes, was the guidance document followed in preparation of this 510k? ☐ ☐

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ISO 11137-1: 2006 Sterilization of Health Care Products- Radiation- Part 1: Requirements for development of validation

CONFORMANCE WITH STANDARD SECTIONS***SECTION NUMBER**

All

SECTION TITLE

All

CONFORMANCE?

Yes



No



N/A

TYPE OF DEVIATION OR OPTION SELECTED *

(b)(4)

DESCRIPTION

(b)(4)

JUSTIFICATION

(b)(4)

SECTION NUMBER**SECTION TITLE****CONFORMANCE?**

Yes



No



N/A

TYPE OF DEVIATION OR OPTION SELECTED ***DESCRIPTION****JUSTIFICATION****SECTION NUMBER****SECTION TITLE****CONFORMANCE?**

Yes



No



N/A

TYPE OF DEVIATION OR OPTION SELECTED ***DESCRIPTION****JUSTIFICATION**

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE ¹

ISO 10993-1 Biological Evaluation of Medical Device- Part 1 Evaluation and Testing (2003)

Please answer the following questions

Yes No

Is this standard recognized by FDA ²? ☒ ☐

FDA Recognition number ³ # 02-98

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? ☒ ☐

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? ☐ ☒
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? ☒ ☐

Does this standard include acceptance criteria? ☒ ☐
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? ☒ ☐
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? ☐ ☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵? ☐ ☒

Were deviations or adaptations made beyond what is specified in the FDA SIS? ☐ ☒
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? ☐ ☒
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard? ☒ ☐
If yes, was the guidance document followed in preparation of this 510(k)? ☒ ☐

Title of guidance: G-95 Blue Book Memorandum: Use of ISO 10993-1

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

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⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ISO 10993-1 Biological Evaluation of Medical Device- Part I Evaluation and Testing (2003)

CONFORMANCE WITH STANDARD SECTIONS***SECTION NUMBER**

All

SECTION TITLE

All

CONFORMANCE?

Yes



No



N/A

TYPE OF DEVIATION OR OPTION SELECTED *

(b)(4)

DESCRIPTION

(b)(4)

JUSTIFICATION

(b)(4)

SECTION NUMBER**SECTION TITLE****CONFORMANCE?**

Yes



No



N/A

TYPE OF DEVIATION OR OPTION SELECTED ***DESCRIPTION****JUSTIFICATION****SECTION NUMBER****SECTION TITLE****CONFORMANCE?**

Yes



No



N/A

TYPE OF DEVIATION OR OPTION SELECTED ***DESCRIPTION****JUSTIFICATION**

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE ¹

ISO 11137-2: 2006 Sterilization of Health Care Products- Radiation- Part 2 Establishing sterilization dose

Please answer the following questions

Yes No

Is this standard recognized by FDA ²? ☒ ☐

FDA Recognition number ³ # 14-225

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? ☒ ☐

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? ☐ ☒
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? ☒ ☐

Does this standard include acceptance criteria? ☒ ☐
If no, include the results of testing in the 510(k).

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If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵? ☐ ☐

Were deviations or adaptations made beyond what is specified in the FDA SIS? ☐ ☒
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? ☐ ☒
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard? ☐ ☒
If yes, was the guidance document followed in preparation of this 510k? ☐ ☐

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ISO 11137-2: 2006 Sterilization of Health Care Products- Radiation- Part 2 Establishing sterilization dose

CONFORMANCE WITH STANDARD SECTIONS***SECTION NUMBER**

All

SECTION TITLE

All

CONFORMANCE?☒ Yes☐ No☐ N/A**TYPE OF DEVIATION OR OPTION SELECTED ***

(b)(4)

DESCRIPTION

(b)(4)

JUSTIFICATION

(b)(4)

SECTION NUMBER**SECTION TITLE****CONFORMANCE?**☐ Yes☐ No☐ N/A**TYPE OF DEVIATION OR OPTION SELECTED *****DESCRIPTION****JUSTIFICATION****SECTION NUMBER****SECTION TITLE****CONFORMANCE?**☐ Yes☐ No☐ N/A**TYPE OF DEVIATION OR OPTION SELECTED *****DESCRIPTION****JUSTIFICATION**

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and 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:

Center for Devices and Radiological Health
1350 Piccard Drive
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 number.

Section 9

Records processed under FOIA Request 2024-4348; Released by CDRH on 10-08-2024

Financial Certification or Disclosure Statement

9. Financial Certification or Disclosure Statement

The requirement for financial certification or disclosure requirements as described in 21 CFR §807.87(i) does not apply to this submission.

PolyRemedy, Inc.
PolyFIT + Absorbing Antimicrobial Dressings

Premarket Notification

13. Substantial Equivalence Discussion

Information on these substantially equivalent devices is provided in APPENDIX 1 of this premarket notification.

The 510(k) "Substantial Equivalence" Decision-Making Process in ODE Guidance Document #K86-3, Guidance on the CDRH Premarket Notification Review Program, was used to determine substantial equivalence (see Figure 4) and compares the attributes of the predicate devices to the PolyFIT⁺ Absorbing Antimicrobial Dressings. Answers to the relevant questions lead to a determination of substantial equivalence, as follows:

1. DOES THE DEVICE HAVE SAME INDICATION STATEMENTS? NO

The indications statement for the PolyFIT⁺ Absorbing Antimicrobial Dressings is highly representative but not identical.

The indications statements for the PolyFIT⁺ Absorbing Antimicrobial Dressings are represented by the predicate device, in whole or in part, as illustrated in the table below:

PolyFIT ⁺ Absorbing Antimicrobial Dressings	PolyFIT Absorbing Dressing (510k exempt)	COPA AMD Antimicrobial Wound Dressing (K071371, K082296)
PolyFIT ⁺ Absorbing Antimicrobial Dressings are intended as effective barriers to inhibit microbial proliferation within the dressing and reduce microbial penetration through the dressing. PolyFIT ⁺ Absorbing Antimicrobial Dressings are for use under a healthcare professional's orders as adjunctive treatment in the management of exudating wounds, partial and full-thickness wounds, such as pressure ulcers (Stages II-IV), lower extremity ulcers (venous or arterial), diabetic foot ulcers, surgical or traumatic wounds (including those left open to heal by secondary intention). They are not intended for wounds with exposed tendon or bone, for 3 rd degree burns or for dry wounds.	Indicated for use under a healthcare professional's orders as adjunctive treatment in the management of exudating wounds, partial and full-thickness wounds, such as pressure ulcers (Stages II-IV), lower extremity ulcers (venous or arterial), diabetic foot ulcers, surgical or traumatic wounds (including those left open to heal by secondary intention). They are not intended for wounds with exposed tendon or bone, for 3 rd degree burns or for dry wounds.	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.

PolyRemedy, Inc.
PolyFIT⁺ + Absorbing Antimicrobial Dressings

Premarket Notification

The table below provides a breakdown of the individual claims, to illustrate the substantial equivalence:

	PolyFIT+ Absorbing Antimicrobial Dressings	PolyFIT Absorbing Dressing (510k exempt)	COPA AMD Antimicrobial Wound Dressing
Antimicrobial claim	Effective barriers to inhibit microbial proliferation within the dressing and reduce microbial penetration through the dressing	None	Antimicrobial agent that protects the dressing from bacterial penetration and colonization. ^a
Use	Use under healthcare professional orders	Use under healthcare professional orders	Prescription use ^a
Conditions	Pressure ulcers (Stages II-IV)	Pressure ulcers	Pressure sores
	Lower extremity ulcers (venous or arterial), diabetic foot ulcers	Lower extremity ulcers, diabetic foot ulcers	Venous stasis ulcers, diabetic ulcers
	Surgical or traumatic wounds (including those left open to heal by secondary intention)	Surgical or traumatic wounds	Abrasions and lacerations
			Post surgical incisions
			Wounds inflicted by trauma
	Partial and full-thickness wounds	Partial and full-thickness wounds	Dermatological disorders
	Partial and full-thickness wounds	Partial and full-thickness wounds	1 st and 2 nd degree burns
	PolyFIT+ Absorbing Antimicrobial Dressings are <u>not</u> intended for full thickness pressure ulcers involving tendon, muscle, bone or third degree burns	PolyFIT Absorbing Dressings are <u>not</u> intended for full-thickness pressure ulcers involving tendon, muscle, bone or third degree burns.	Unstated

^a As stated in the Summary of Safety and Effectiveness, K071371, K082296

PolyRemedy, Inc.
PolyFIT + Absorbing Antimicrobial Dressings

Premarket Notification

2. DO THE DIFFERENCES ALTER THE INTENDED THERAPEUTIC/DIAGNOSTIC EFFECT?

.....No
 Although there are minor differences between the indications statements of the predicate devices and the PolyFIT+ Absorbing Antimicrobial Dressings, the intended therapeutic effects are the same.

3. DOES NEW DEVICE HAVE THE SAME TECHNOLOGICAL CHARACTERISTICS, E.G., DESIGN, MATERIALS, ETC.?

..... YES

PolyFIT+ Absorbing Antimicrobial Dressings have similar technological characteristics when compared to the predicate device (e.g. materials, body site application, single use). The table below illustrates the similarities and differences in technological characteristics:

	PolyFIT+ Absorbing Antimicrobial Dressing	PolyFIT Absorbing Dressing (510k exempt)	COPA AMD Antimicrobial Wound Dressing
Antimicrobial agent	PHMB	None	PHMB
Concentration	0.3%	N/A	0.5%
Method of application to device	Embedded	N/A	Impregnated
Mechanism of agent release	No release	N/A	Unknown
Single use	Yes	Yes	Yes
Material	Micro-fibers (Synthetic polymers)	Micro-fibers (Synthetic polymers)	Micro-fibers (polyurethane foam)
Geometry	2" x 2" 4" x 4" 5" x 5"	2" x 2" 4" x 4" 5" x 5"	2" x 2" 3.5" x 3" 4" x 4" 4" x 8" 6" x 6" 8" x 8"
Function	Absorbs exudate; / microbial protection	Absorbs exudate	Absorbs exudate; / microbial protection
Anatomical Site	Skin surface wounds	Skin surface wounds	Skin surface wounds
Treatment time	Up to 7 days	Up to 7 days	Up to 7 days
Conformable to wound bed	Yes	Yes	Yes
Non-adherent	Yes	Yes	Yes
Provided Sterile	Yes	Yes	Yes
Sterilization	Gamma	Gamma	Gamma

PolyRemedy, Inc.
 PolyFIT + Absorbing Antimicrobial Dressings

Premarket Notification

	PolyFIT+ Absorbing Antimicrobial Dressing	PolyFIT Absorbing Dressing (510k exempt)	COPA AMD Antimicrobial Wound Dressing
Method			

4. ARE THE DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH TO ENSURE EQUIVALENCE? YES

The descriptive characteristics of antimicrobial wound dressings are reasonably precise. PolyFIT+ Absorbing Antimicrobial Dressings and the COPA AMD Antimicrobial Wound Dressing are all placed at the skin surface wound site. Both dressings utilize PHMB as the antimicrobial agent. Both dressings are provided sterile and intended for single use. Both dressings may remain in place for a period of up to 7 days.

Both dressings are manufactured from biocompatible materials which absorb exudate and inhibit bacterial proliferation. Both dressings are offered in standard geometric configurations, which are consistent with commonly used wound dressing dimensions. Both the PolyFIT+ Absorbing Antimicrobial dressings and the COPA AMD wound dressings have non-adherent material qualities which prevent adherence of the dressing to the tissue within the wound.

PolyFIT+ Absorbing Antimicrobial Dressings are substantially equivalent to the identified predicate devices in terms of intended use, materials, physical characteristics and performance characteristics.

5. ARE PERFORMANCE DATA AVAILABLE TO ASSESS EQUIVALENCE? YES

Performance data assessing the safety and effectiveness of the PolyFIT+ Absorbing Antimicrobial Dressings are included in this premarket notification submission to adequately assess and report on the device performance. Performance data were based on well-known characteristics common to the predicate devices, and the FDA draft guidance document "Premarket Notification (510k) Submissions for Medical Devices that Include Antimicrobial Agents" dated July 19, 2007.

6. DOES THE PERFORMANCE DATA DEMONSTRATE EQUIVALENCE? YES

The performance data submitted in this premarket notification clearly demonstrate equivalence between the PolyFIT+ Absorbing Antimicrobial Dressings, the COPA AMD Antimicrobial Wound Dressing and the PolyFIT Absorbing Wound Dressings.

7. REASON FOR PREMARKET NOTIFICATION?

Commercial distribution of a new substantially equivalent device.

CONCLUSION:

PolyFIT+ Absorbing Antimicrobial Dressings and the COPA AMD Wound Dressing are both intended as effective barriers to inhibit microbial proliferation within the

PolyRemedy, Inc.
PolyFIT + Absorbing Antimicrobial Dressings

Premarket Notification

dressings and reduce microbial penetration through the dressing. PolyFIT+ Absorbing Antimicrobial Dressings, the COPA AMD Wound Dressings and the PolyFIT Absorbing Wound Dressings are all intended for the absorption of wound exudate. With the exception of the addition of PHMB, PolyFIT+ Absorbing Antimicrobial Dressings and the PolyFIT Absorbing Wound Dressing are fabricated from identical materials with identical use (single use only) characteristics. PolyFIT+ Absorbing Antimicrobial Dressings are substantially equivalent, in terms of intended use, principle of operation, technological characteristics, and performance characteristics to the COPA AMD Antimicrobial Wound Dressing predicate.

PolyRemedy, Inc.
PolyFIT + Absorbing Antimicrobial Dressings

Premarket Notification

Section 13

Substantial Equivalence Discussion

**510(K) "SUBSTANTIAL EQUIVALENCE" DECISION MAKING PROCESS
FOR THE PolyFIT+ Antimicrobial Absorbing Wound Dressing.**

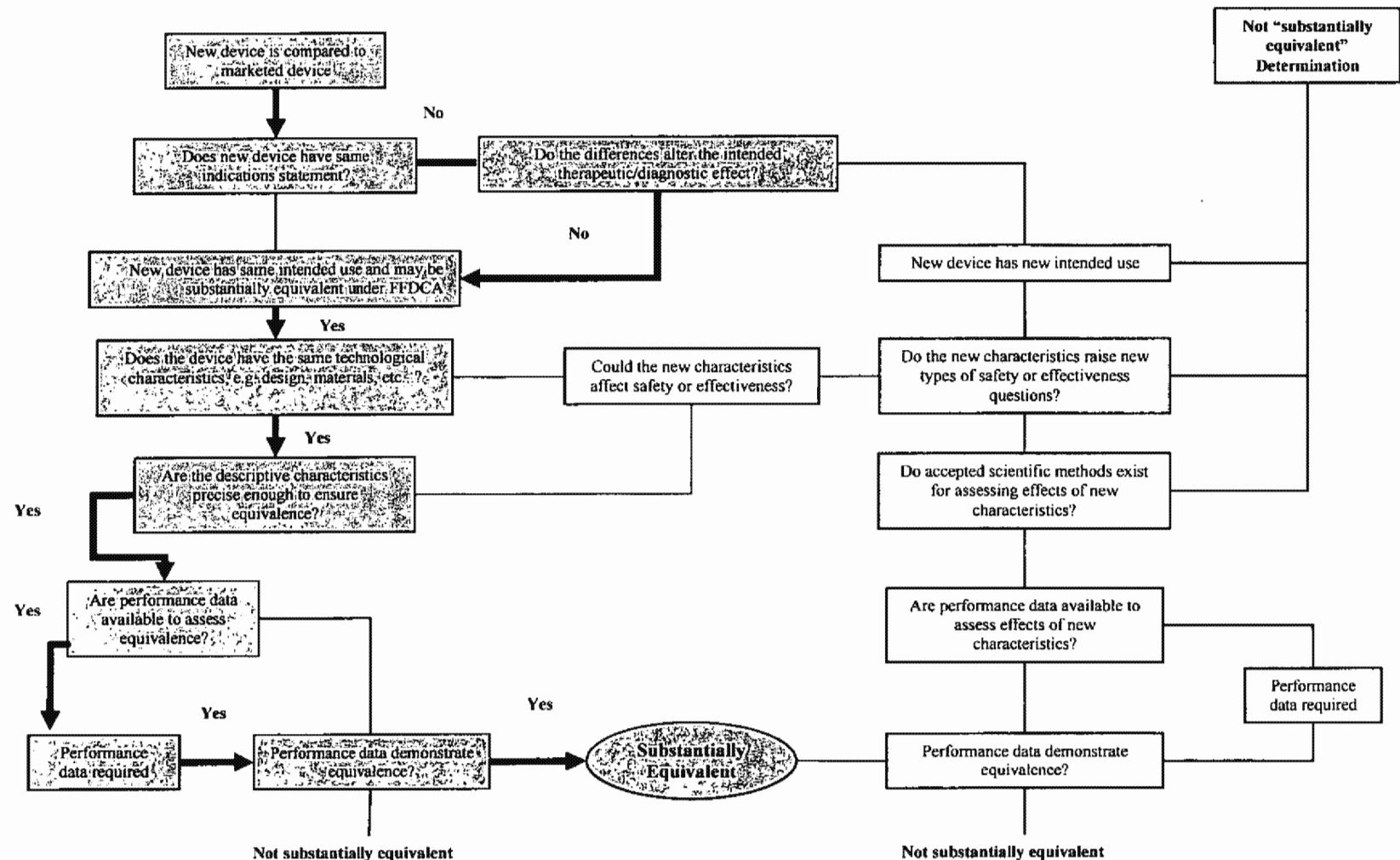


Figure 2. Substantial Equivalence Decision Making Process for the PolyFIT+ Antimicrobial Absorbing Wound Dressing.

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PolyFIT + Absorbing Antimicrobial Dressings

Premarket Notification

8. Class III Summary and Certification

PolyFIT™+ Absorbing Antimicrobial Dressings and PolyFIT™+ High Absorbing Antimicrobial Dressings are pre-amendment unclassified medical devices. The Class III Summary and Certification requirement as described in 21 CFR §807.87(j) and §807.94 do not apply to this device and submission.

PolyRemedy, Inc.
PolyFIT + Absorbing Antimicrobial Dressings

Premarket Notification



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

APR - 8 2010

Poly Remedy, Inc.
% Mr. Gary Mocnik
2637 Marine Way, Suite 100
Mountain View, California 94043

Re: K092351

Trade/Device Name: PolyFIT™ + Absorbing Antimicrobial Dressings and
PolyFIT™ + High Absorbing Antimicrobial Dressings

Regulatory Class: Unclassified

Product Code: FRO

Dated: March 26, 2010

Received: March 29, 2010

Dear Mr. Mocnik:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

Page 2 - Mr. Gary Mocnik

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.

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

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



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

Enclosure

5. Indications for Use Statement

K092351 1/1

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K092351Device Name: **PolyFIT™+ Absorbing Antimicrobial Dressings and PolyFIT™+ High Absorbing Antimicrobial Dressings**

Indications for Use:

PolyFIT+ Absorbing Antimicrobial Dressings are intended as effective barriers to inhibit microbial proliferation within the dressing and reduce microbial penetration through the dressing. PolyFIT+ Absorbing Antimicrobial Dressings are for use under a healthcare professional's orders as adjunctive treatment in the management of exudating wounds, partial and full-thickness wounds, such as pressure ulcers (Stages II-IV), lower extremity ulcers (venous or arterial), diabetic foot ulcers, surgical or traumatic wounds (including those left open to heal by secondary intention). They are not intended for wounds with exposed tendon or bone, for 3rd degree burns or for dry wounds.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krane

(Division Sign-Off)

Division of Surgical, Orthopedic,
and Restorative Devices510(k) Number K092351

Page 1 of _____

Section 18

Records processed under FOIA Request 2024-4348; Released by CDRH on 10-08-2024

Electromagnetic Compatibility And Electrical Safety

18. Electromagnetic Compatibility and Electrical Safety

This section does not apply.

PolyRemedy, Inc.
PolyFIT + Absorbing Antimicrobial Dressings

Premarket Notification

10. Declaration of Conformity And Summary Reports

This submission is a traditional 510(k) submission. The requirement for a declaration of conformity and a summary report of testing does not apply.

PolyRemedy, Inc.
PolyFIT + Absorbing Antimicrobial Dressings

Premarket Notification

Section 2

Certification of Compliance- ClinicalTrials.gov

~~Records processed under FOIA Request 2024-4348, Released by CDRH on 10-08-2024~~

2. **Certification of Compliance with ClinicalTrials.gov FDA Form 3674**
(See attached)

PolyRemedy, Inc.
PolyFIT + Absorbing Antimicrobial Dressings

Premarket Notification

000003

Records processed under FOIA Request 2024-4348; Released by CDRH on 10-08-2024



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

**Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with
Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))**

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR/APPLICANT/SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER PolyRemedy, Inc.	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES Jun 30, 2009
3. ADDRESS (Number, Street, State, and ZIP Code) 2637 Marine Way, Suite 100, Mountain View, CA 94043	4. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) 650.960.2404 (Fax) 650.960.2406

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

PolyRemedy PolyFIT Absorbing Antimicrobial Dressings

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (If number previously assigned)

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES (See instructions for additional information and explanation)

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES (Attach extra pages as necessary)

NCT Number(s): _____

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331; section 301 of the Federal Food, Drug, and Cosmetic Act.

Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)	12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11 (Name) Dan Eckert (Title) President, CEO	
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12) 2637 Marine Way, Suite 100, Mountain View, CA 94043	14. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) 650.960.2404 (Fax) 650.960.2406	15. DATE OF CERTIFICATION Jun 30, 2009

Form FDA 3674 (11/08) (FRONT)

PSC Graphics: (301) 443-1090 EF

Section 21

Records processed under FOIA Request 2024-4348; Released by CDRH on 10-08-2024

Clinical Data

21. Clinical Data

This section does not apply.

PolyRemedy, Inc.
PolyFIT+ Absorbing Antimicrobial Dressings

Premarket Notification



2637 Marine Way, Suite 100
Mountain View, CA 94043
P: 650.960.2404
F: 650.960.2406
www.polyremedy.com

November 20, 2009

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC

NOV 23 2009

Received

Attn: David Krause, Ph.D., George Ngatha

K-SY

Re: K092351

Trade Name: Poly Fit + Absorbing & High Absorbing Antimicrobial Dressings
Email communication dated October 20, 2009

Dear Sirs:

To adequately respond to your email dated October 20, 2009 requesting additional information necessary to complete the review of the above reference premarket notification, we are requesting an extension of 180 days.

We appreciate the agency's consideration and review of this submission and if there are any questions regarding this information, please do not hesitate to contact me at (b)(6)

Please also note that PolyRemedy has retained Jonathan Kahan, of Hogan & Hartson, L.L.P. as regulatory counsel to assist in this 510(k) submission. Please accept this correspondence as the company's authorization for Mr. Kahan and his firm to discuss this submission with FDA on behalf of PolyRemedy.

Sincerely,

(b)(6)

Gary Mocnik
Official Correspondent
Poly Remedy, Inc.
garym@polyremedy.com

14. Proposed Labeling

The following sections contain the proposed instructions for use for the PolyFIT+ Absorbing Antimicrobial Dressings (Section 14.1) and the proposed labeling (Section 14.2).

14.1 Instructions for use

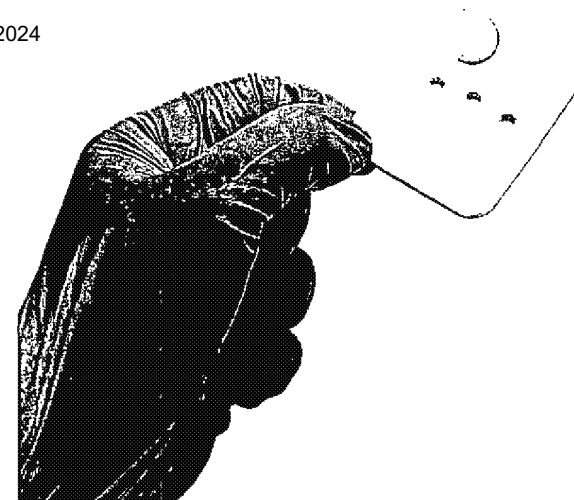
PolyRemedy, Inc.
PolyFIT + Absorbing Antimicrobial Dressings

Premarket Notification



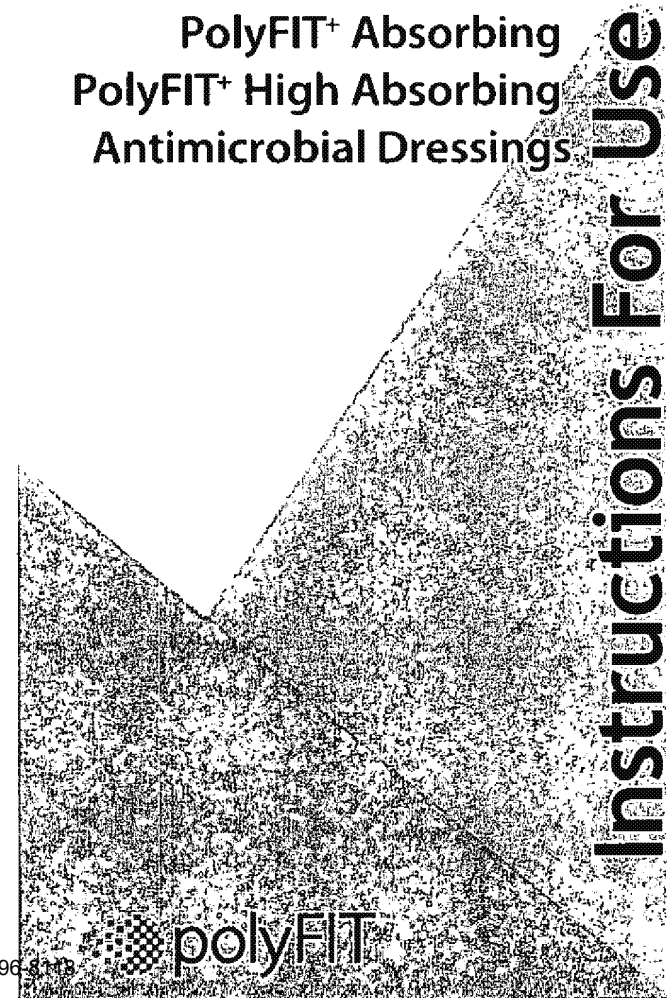
PolyRemedy, Inc.
2637 Marine Way, Suite 100
Mountain View, CA 94043

Call: 1.866.609.3515
Or Visit: www.polyremedy.com



**PolyFIT⁺ Absorbing
PolyFIT⁺ High Absorbing
Antimicrobial Dressings**

Instructions For Use



000051
156

Indications for Use

PolyFIT⁺ Absorbing Antimicrobial Dressings are intended as effective barriers to inhibit microbial proliferation within the dressing and reduce microbial penetration through the dressing. PolyFIT⁺ Antimicrobial Dressings are for use under a healthcare professional's orders as adjunctive treatment in the management of exuding wounds, partial and full-thickness wounds, such as pressure ulcers (Stages II-IV), lower extremity ulcers (venous or arterial), diabetic foot ulcers, surgical or traumatic wounds (including those left open to heal by secondary intention). They are not intended for wounds with exposed tendon or bone, for 3rd degree burns or for dry wounds. Contains Polyhexamethylene Biguanide (PHMB) 0.3%.

Call your Doctor if you Notice any of the Following

- Change in the color, consistency or amount of wound drainage.
- Redness or warmth around the wound.
- Increased pain or tenderness at the wound site.
- Unusual odor from the wound.

Precautions and Warnings



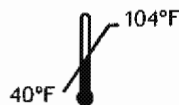
Sterile by gamma radiation.



Sterile unless damaged or opened.



Single use.



Store between 40° F and 104° F.



CAUTION! Federal law restricts this device to sale by or on the order of a physician or properly licensed healthcare practitioner.

Product Information

For additional information about PolyRemedy or PolyFIT⁺ dressings

Call: 1.866.609.3515

Visit: www.polyremedy.com

Changing your Dressing

1. Using clean technique, carefully remove your soiled dressing and discard.
2. Clean your wound according to your healthcare practitioner's instructions and discard materials.
3. Wash hands and put on clean gloves, if ordered by your healthcare practitioner.
4. Apply any additional prescribed creams, ointments or products on your wound as instructed.
5. Open the PolyFIT⁺ dressing and apply PolyFIT⁺ dressing with the DOTS DOWN against your wound.
6. Apply any outer dressings to secure in place as directed.
7. If you have been instructed to wear a special shoe, stockings or any other additional treatment, apply it as instructed.

14.2 Primary Labeling

**PolyFIT+ Absorbing
Antimicrobial Dressing**

Contains: Polyhexamethylene Biguanide (PHMB) - 0.3%
4x4 inches/10x10 cm



Manufactured on:

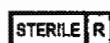


Use by:

Contents: 1/pouch
Product Code: PFM44A-P

PolyRemedy
2637 Marine Way, Suite 100
Mountain View, CA 94043

1.866.609.3515
www.polyremedy.com

Sterile by
gamma radiationSterile unless
damaged or opened

Single use

Consult Instructions
for useStore Between
40°F and 104°F

Caution: Federal law restricts this
device to sale only on the order of
a physician or properly licensed
healthcare practitioner

PN: 23-50348-SF01rA LOT

PolyFIT+ Absorbing Antimicrobial Dressing Label

PolyRemedy, Inc.
PolyFIT + Absorbing Antimicrobial Dressings

Premarket Notification



**PolyFIT+ High Absorbing
Antimicrobial Dressing**

Contains: Polyhexamethylene Biguanide (PHMB) - 0.3%
4x4 inches/10x10 cm



Manufactured on:



Use by:

Contents: 1/pouch
Product Code: PFM44A-SP

PolyRemedy
2637 Marine Way, Suite 100
Mountain View, CA 94043

1.866.609.3515
www.polyremedy.com

STERILE R

Sterile by
gamma radiation



Sterile unless
damaged or opened



Single use

PN: 23-50352-SF01rA LOT



Consult instructions
for use



Store Between
40°F and 104°F

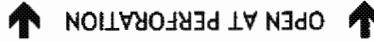


Caution: Federal law restricts this
device to sale only on the order of
a physician or properly licensed
healthcare practitioner

PolyFIT+ High Absorbing Antimicrobial Dressing Label

PolyRemedy, Inc.
PolyFIT + Absorbing Antimicrobial Dressings

Premarket Notification



polyFIT⁺ Absorbing
Antimicrobial Dressing
4x4 inches/10x10 cm



**PolyFIT+ Absorbing
Antimicrobial Dressing**

Contains: Polyhexamethylene Biguanide (PHMB) - 0.3%

4x4 inches/10x10 cm



Contents: 5/box
Product Code: PFM44A-P

PolyRemedy
2637 Marine Way, Suite 100
Mountain View, CA 94043

1.866.609.3515
www.polyremedy.com



Sterile by
gamma radiation



Consult instructions
for use



Sterile unless
damaged or opened



Store between
40°F and 104°F



Single use

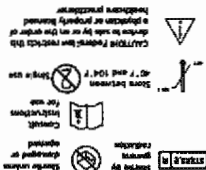


CAUTION! Federal law restricts this
device to sale by or on the order of
a physician or properly licensed
healthcare practitioner

PK 23-50360-5F01A LOT



PolyFIT+ Absorbing
Antimicrobial Dressing
4x4 inches/10x10 cm

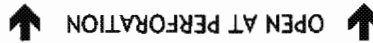


Product Code: PFM44A-P
4x4 inches/10x10 cm
Antimicrobial Dressing
PolyFIT+ Absorbing
polyFIT⁺

PolyFIT+ Absorbing Antimicrobial Dressing Box Label

PolyRemedy, Inc.
PolyFIT + Absorbing Antimicrobial Dressings

Premarket Notification



PolyFIT[™] High Absorbing
Antimicrobial Dressing
4x4 inches/10x10 cm



**PolyFIT+ High Absorbing
Antimicrobial Dressing**

Contains: Polyhexamethylene Biguanide (PHMB) - 0.3%

4x4 inches/10x10 cm



Contents: 5/box
Product Code: PFM44A-SP

PolyRemedy
2637 Marine Way, Suite 100
Mountain View, CA 94043

1.866.609.3515
www.polyremedy.com



Sterile by
gamma radiation



Consult instructions
for use



Sterile unless
damaged or opened



Store between
40°F and 104°F



Single use



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a physician or properly licensed
healthcare practitioner

Ptc 21-50383-SP011A LCB



PolyFIT+ High Absorbing
Antimicrobial Dressing
4x4 inches/10x10 cm

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Store between
40°F and 104°F

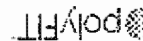
Consult
instructions
for use

Sterile by
gamma radiation

Product Code: PFM44A-SP

4x4 inches/10x10 cm

PolyFIT+ High Absorbing
Antimicrobial Dressing



PolyFIT+ High Absorbing Antimicrobial Dressing Box Label

PolyRemedy, Inc.
PolyFIT + Absorbing Antimicrobial Dressings

Premarket Notification

15. Sterilization and Shelf Life

Sterility

The PolyFIT+ Absorbing Antimicrobial Dressings will be sterilized using gamma irradiation. The Sterility Assurance Level for the PolyFIT+ Absorbing Antimicrobial Dressings will be 10^{-6} . The sterilization cycle will be 25 kGy as a sterilization dose. The sterilization cycle was validated following ISO11137-1/2: Sterilization of Health Care Products - Radiation Sterilization. The specific method selected was VDMax- 25kGy minimum dose. The radiation dose range for the sterilization cycle is within the range of 25 kGy - 40 kGy.

The sterilization is conducted at a qualified FDA registered facility: (b)(4)

(b)(4)

Packaging Description

The sterile barrier materials of the PolyFIT+ Absorbing Antimicrobial Dressings are the same as those commonly used in the medical device industry.

The packaging for the device consists of:

- Pouch: White PE/Foil, 7" x 10"
- Unitary (Primary) Box: White Chipboard, 7" x 1 1/2" x 10-1/4"
- Shipping Carton- White Cardboard, 7-1/4" x 1-11/16" x 10-5/8"

The packaging material, process and product orientation/geometry assure the sterile barrier maintains the established sterility assurance level.

The labeling of the PolyFIT+ Absorbing Antimicrobial Dressings includes the Instructions for Use and the packaging labeling.

Shelf Life

The shelf-life for the PolyFIT+ Absorbing Antimicrobial Dressings is: (b)(4)

The shelf-life will be validated using industry-standard accelerated aging techniques, (b)(4)

(b)(4)

The shelf-life validation will include

(b)(4)

Packaging

integrity will be validated using (b)(4)

(b)(4)

PolyRemedy, Inc.
PolyFIT + Absorbing Antimicrobial Dressings

Premarket Notification