



U.S. Department of Health & Human Services

Food and Drug Administration

FOIA RESPONSE

USER: (ixg)
FOLDER: K080620 - 135 pages (FOI:11002717)
COMPANY: 3M COMPANY-3M HEALTH CARE (3M3MHEALCARE)
PRODUCT: DRESSING, WOUND, DRUG (FRO)
SUMMARY: Product: MODIFICATION TO 3M TEGADERM CHG DRESSING

DATE REQUESTED: Oct 5, 2011

DATE PRINTED: Oct 5, 2011

Note: Releasable Version



K080620

Premarket Notification (510(k)) Summary

1. Sponsor Information:

MAY 19 2008

3M Health Care
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144-1000

Contact Person: Maria Ruiz
Senior Regulatory Affairs Associate
Phone Number: (651) 736-2733
FAX Number: (651) 737-5320

Date of Summary: April 18, 2008

2. Device Name and Classification:

Common or Usual Name: Antimicrobial I.V. Securement Dressing

Proprietary Name: 3M™ Tegaderm™ CHG Dressing
(Chlorhexidine Gluconate I.V. Securement Dressing)

Classification Name: Antimicrobial Dressing, Unclassified

Performance Standards: None

3. Predicate Devices:

- 3M™ Tegaderm™ CHG Dressings (K063458, cleared April 5, 2007)
- Biocclusive Transparent Film Dressing (K895207, cleared September 28, 1989)
- Opsite IV 3000 (K895353, cleared December 14, 1989)
- Tegaderm™ Transparent Film Dressings (K973036, cleared November 12, 1997)
- SorbaView® Ultimate Window Dressing
- SorbaView® 2000

4. Description of Device:

3M™ Tegaderm™ CHG Dressing, Chlorhexidine Gluconate I.V. Securement Dressing, is used to cover and protect catheter sites and to secure devices to skin. Available in a variety of shapes and sizes to meet the needs of the caregiver.

Tegaderm™ CHG Dressing consists of a transparent adhesive dressing and an integrated pad containing Chlorhexidine Gluconate (CHG), a well-known antiseptic agent with broad-spectrum antimicrobial and antifungal activity. The dressing is a barrier to liquid (waterproof), bacteria and viruses* and yeast, and

protects the IV site from outside contamination. The pad absorbs up to eight times its weight in fluid. *In vitro* testing (log reduction, barrier, and zone of inhibition) demonstrates that the Tegaderm™ CHG dressing has an antimicrobial effect against, and is a barrier to, the passage of a variety of gram-positive and gram-negative bacteria and yeast in the dressing. Tegaderm™ CHG Dressing is transparent, allowing continual site observation, and is breathable, allowing good moisture vapor exchange.

**In vitro* testing has proven that Tegaderm CHG provides a viral barrier from viruses 27 nm in diameter, (e.g. HCV) or larger (e.g. HBV and HIV) while the dressing remains intact without leakage.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 19 2008

3M Health Care
% Ms. Maria Ruiz
Senior Regulatory Affairs Associate
3M Center, Building 275-5W-06
St. Paul, Minnesota 55144-1000

Re: K080620

Trade/Device Name: 3M™ Tegaderm™ CHG Dressing, (Chlorhexidine Gluconate I.V. Securement Dressing)

Regulatory Class: Unclassified

Product Code: FRO

Dated: April 18, 2008

Received: April 22, 2008

Dear Ms. Ruiz:

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

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

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

Page 2 – Ms. Maria Ruiz

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (if known): K080620

Device Name: 3M™ Tegaderm™ CHG Dressing,
(Chlorhexidine Gluconate I.V. Securement Dressing)

Indications for Use:

3M™ Tegaderm™ CHG Dressings (Chlorhexidine Gluconate I.V. Securement Dressing), can be used to cover and protect catheter sites and to secure devices to skin. Common applications include IV catheters, other intravascular catheter and percutaneous devices.

Prescription Use X OR Over-The-Counter-Use
(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for M42
(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

Attachment 2 - 2

510(k) Number K080620



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 19 2008

3M Health Care
% Ms. Maria Ruiz
Senior Regulatory Affairs Associate
3M Center, Building 275-5W-06
St. Paul, Minnesota 55144-1000

Re: K080620

Trade/Device Name: 3M™ Tegaderm™ CHG Dressing, (Chlorhexidine Gluconate I.V.
Securement Dressing)

Regulatory Class: Unclassified

Product Code: FRO

Dated: April 18, 2008

Received: April 22, 2008

Dear Ms. Ruiz:

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.

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Page 2 – Ms. Maria Ruiz

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Sincerely yours,



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

Enclosure

Indications for Use Statement

510(k) Number (if known): K080620

Device Name: 3M™ Tegaderm™ CHG Dressing,
(Chlorhexidine Gluconate I.V. Securement Dressing)

Indications for Use:

3M™ Tegaderm™ CHG Dressings (Chlorhexidine Gluconate I.V. Securement Dressing), can be used to cover and protect catheter sites and to secure devices to skin. Common applications include IV catheters, other intravascular catheter and percutaneous devices.

Prescription Use X OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogle for M42
(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

Attachment 2 - 2

510(k) Number K080620



APR 10 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

3M Health Care
% Ms. Maria Ruiz
Senior Regulatory Affairs Associate
3M Center, Building 275-5W-06
St. Paul, Minnesota 55144-1000

Re: K080620
Trade Name: Tegaderm CHG Dressing
Dated: February 29, 2008
Received: March 16, 2008

Dear Ms. Ruiz:

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

1. You submitted a device description that includes the following claim, "CHG incorporated into the gel pad inhibits bacterial growth". Please be advised that performance claims should be supported with data. The text of the labeling claims should be data-driven and limited to the summary of the testing methods and results obtained. It is expected that for antibacterial claims the claim will be the data demonstrating that the wound dressing has an antibacterial effect against tested microorganisms *in vitro*, and the wound dressing is a barrier to the passage of the specific microorganisms tested. The statement, "CHG incorporated into the gel pad inhibits bacterial growth" does not follow these guidelines, therefore, it is not acceptable. You agreed in K063458 to remove "CHG incorporated into the gel pad inhibits bacterial growth" and replace it with "*In vitro testing (log reduction, barrier, and zone of inhibition) demonstrates that the Tegaderm™ CHG dressing has an antimicrobial effect against, and is a barrier to, the passage of a variety of gram-positive and gram-negative bacteria and yeast.*" Please revise this claim and any other similar claims, so that they follow these guidelines.
2. You submitted viral penetration testing on bacteriophage in support of your claim that the subject device acts as a barrier to viruses. The data you submitted is not sufficient to demonstrate that the subject device is a barrier to all viruses. Please submit viral testing using model viruses which are small enough in size to demonstrate that various larger viruses will not penetrate the device. Additionally, please submit a predicate device for which the subject device will be substantially equivalent with regard to a wound dressing acting as a viral barrier. In the absence of a predicate device, please provide clinical data to support this claim.

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3. You have stated that you plan to market a (b)(4) of your Tegaderm CHG and (b)(4) Tegaderm CHG (b)(4). We are not able to provide (b)(4) Tegaderm CHG was cleared as an individually sterilized device. If your subject device will be included as a (b)(4) marketed with the subject device needs to be assessed (b)(4) (b)(4) (b)(4)
4. Your Special 510(k) does not include a Design Control Activities Summary (DCAS). An adequate Design Control Activities Summary is an essential part of a Special 510(k) submission. Therefore, please provide a DCAS which identifies specific information on the device modifications, all risks which result from these changes, verification activities, and specific (quantitative) acceptance criteria, and results of verification. To elaborate, the DCAS should address potential risks due to the noted changes. Any relevant changes in the manufacturing process, including the sterilization method, should be considered as well. See attachment for further explanation of the Design Control Activities Summary.
5. Please provide a revised Truthful and Accuracy statement that correctly states "as required by 21 CFR 807.87 (k)" not 21 CFR 807.87 (j).

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

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

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

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from

our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. 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/cdrh/mdufma/guidance/1219.html>.

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

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

If you have any questions concerning the contents of the letter, please contact Suzanne Malli at (240) 276-3621. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (240) 276-3150, or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



David Krause, Ph.D.
Chief, Plastic and Reconstructive
Surgery Branch
Division of General, Restorative,
and Neurological Devices

Generic "Design Control Activities Summary"

Device Modification	Risk	Verification Activity	Acceptance Criteria	Results of Verification
<p>Sponsor should identify each difference between the modified device and the predicate (cleared) device</p>	<p>Sponsor should identify all risks associated with each modification</p>	<p>Sponsor should identify the analysis(es) performed to address each identified risk. Sponsor should either state the same testing protocol submitted in the predicate submission was used or be prepared to make available the protocol describing the tests performed.</p> <p>If the protocol conforms to a standard, sponsor shall provide:</p> <ul style="list-style-type: none"> • a statement whether the test method was in <u>full</u> accordance with a particular standard • a description of all modifications to the standard made during testing, if any, and • a complete description of those parameters not defined in the cited standard <p>If the protocol does not conform to a standard, a summary of the test conditions shall be provided.</p> <p>In addition, the sponsor shall identify the specific device components tested, the number of components tested, and provide a rationale for why the test conditions and components tested were considered "worst-case".</p>	<p>Sponsor should identify the quantitative acceptance criterion(ia) applied to the analysis(es) performed, provide a rationale for the acceptance criterion(ia) identified, and, if appropriate, state that failure modes shall be consistent with those reported for predicate device; then, list those failure modes</p>	<p>Sponsor should provide a description of how the results of the analysis(es) met the acceptance criteria and include a description of the failure modes, if appropriate.</p>

Sample "Design Control Activities Summary"

Modification	Risk	Verification Activity	Acceptance Criteria	Results of Verification
<p>Modification of Component "A" by decreasing diameter by 2mm.</p>	<p>Device may be susceptible to compression failure</p>	<p>Testing conducted in full accordance with ASTM F000, as in our predicate Submission. The following parameters, not defined by ASTM F000, were used: testing was performed on 5 samples. "A.0001" was tested. Component "A.0001" has the smallest critical dimension; therefore it was considered the "worst-case" component. These testing parameters are the same as those used in the clearance of K00000.</p>	<p>When tested in accordance with ASTM F000, the component tested will maintain a compression strength of 1000N. These values are equal to those previously reported for the predicate device cleared in K000000. The failure modes shall be consistent with those reported for predicate device (i.e., fracture at the critical dimension)</p>	<p>All samples tested (n=5) met the acceptance criteria. The range for the compression strength was 1410N to 2070N.</p>

H:\DGRND\PRSB\Design Control Activities Summary Tables

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cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-410 (DGRND/PRSB)
D.O.
f/t:SWM:tlm:4-9-08

HFZ	Last Name	Date	HFZ	Last Name	Date	HFZ	Last Name	Date
HFZ410	Malli	04/29/02						
2410	Krane	7/10/08						

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

March 17, 2008

3M COMPANY-3M HEALTH CARE
MEDICAL DIVISION
3M CENTER, BLDG. 275-5W-06
ST. PAUL, MN 55144
ATTN: MARIA RUIZ

510(k) Number: K080620
Received: 14-MAR-2008
Product: MODIFICATION TO 3M
TEGADERM CHG
DRESSING

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

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

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

A new provision of the Food and Drug Administration Amendments Act of 2007, 42 U.S.C. 282(j)(5)(B), requires that a certification form (<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf>) accompany all 510(k)/HDE/PMA submissions on or after December 26, 2007. You are responsible for registering certain device clinical trials in the Clinical Trials Data Bank (<http://prsinformo.clinicaltrials.gov>). If your submission does not include FDA Form 3674, please send 2 hardcopies of the completed certification form referencing the submission number identified above. Additional information about the new certification

form may be found at the following link to the Federal Register Notice (<http://www.fda.gov/OHRMS/DOCKETS/98fr/07-6023.htm>).

Please note the following documents as they relate to 510(k) review:
1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1655.pdf>. Please refer to this guidance for information on a formalized interactive review process.
2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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

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

Sincerely yours,

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

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

March 05, 2008

3M COMPANY-3M HEALTH CARE
MEDICAL DIVISION
3M CENTER, BLDG. 275-5W-06
ST. PAUL, MN 55144
ATTN: MARIA RUIZ

510(k) Number: K080620
Received: 04-MAR-2008
User Fee ID Number: 6035140
Product: MODIFICATION TO 3M
TEGADERM CHG
DRESSING

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

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) and the FDA Amendments Act of 2007 (FDAAA) (Public Law 110-85), authorizes FDA to collect user fees for certain types of 510(k) submissions. The submission cannot be accepted for review until the fee is paid in full ; therefore, the file has been placed on hold. When your user fee payment has been received , review of the 510(k) will resume as of that date. Alternatively, you may request withdrawal of your submission. Please send a check to one of the addresses listed below:

By Regular Mail

By Private Courier(e.g., Fed Ex, UPS, etc.)

Food and Drug Administration
P.O. Box 956733
St. Louis, MO 63195-6733.

U.S. Bank
956733
1005 Convention Plaza
St. Louis, MO 63101
(314) 418-4983

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (240)276-4025 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at www.fda.gov/oc/mdufma.

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

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file a 510k Submission with FDA or what type of submission to submit, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (240) 276-3150 or its toll-free number (800)638-2041, or contact them at their Internet address www.fda.gov/cdrh/dsma/dsmastaf.html, or you may submit a 513(g) request for information regarding classification to the Document Mail Center at the address above. If you have any questions concerning receipt of your payment, please contact Christina Zeender at Christina.Zeender@fda.hhs.gov. If you have questions regarding the status of your 510(k) Submission, please contact DSMICA at the numbers or address above.

Sincerely yours,

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

K080620

Special 510(k): Device Modification



February 29, 2008

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

Received

MAR - 4 2008

FDA CDRH DMC

Reference : K063458, 3M™ Tegaderm™ CHG Dressing
Chlorhexidine Gluconate I.V. Securement Dressing
Cleared April 5, 2007

Dear Madam/Sir:

3M Health Care hereby submits this **Special 510(k): Device Modification** to request a modification for our product, 3M™ Tegaderm™ CHG Dressing. The modification is to add a viral barrier claim (b)(4). We believe these modifications are eligible for the Special 510(k) process since they have the same fundamental scientific technology and intended use as the predicate device.

We consider our intent to market this device as confidential commercial information and requests that it be treated as such by FDA. We have taken precautions to protect the confidentiality of the intent to market these devices. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

Thank you in advance for your consideration of our application. If there are any questions, please feel free to contact me at 651-736-2733.

A payment (check No. (b)(4)) in the amount of (b)(4) was made to FDA on February 28, 2008 in support of this submission, and 3M's Medical Device User Fee Payment Identification Number for this submission is (b)(4) (form attached). Should you have any questions regarding this submission, please feel free to contact me.

Sincerely,

Maria Ruiz
Senior Regulatory Affairs Associate
3M Health Care Regulatory Affairs

K25
FSU
UNCLASSIFIED

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET	PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.
A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:	
<ol style="list-style-type: none"> 1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent. 2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check. 3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (Note: In no case should payment be submitted with the application.) 4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.) 5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer. 6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center. 	
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) 3M COMPANY CORP 3M COMPANY CORP 3M CENTER BLDG 275-5W-06 ST. PAUL MN 55144-1000 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)(4)	2. CONTACT NAME Maria Ruiz 2.1 E-MAIL ADDRESS meruiz@mmm.com 2.2 TELEPHONE NUMBER (include Area code) 651-736-2733 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 651-737-5320
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma)	
Select an application type: <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice	3.1 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:	
5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.	
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially	
6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).) <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	
7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b)(4)	

25-Feb-2008

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Special 510 (k)

3M™ Tegaderm™ CHG Dressing Modification

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7. Device Description and Comparison
8. Substantial Equivalence
9. Summary of Design Control Activities
10. 510(k) Summary
11. Truthful and Accuracy Certification

Attachments

1. Draft Labels and Instructions for Use
2. Indications for Use Statement
3. Declaration of Conformity with Design Controls
4. 510(k) Summary
5. Certification of Truthfulness and Accuracy
6. Viral Penetration Study, Laboratory Study Report No. 377857
7. (b)(4)

Section 1

Cover Sheet
Form FDA 3514

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission 7/29/2008	User Fee Payment ID Number MD6035140-956733	FDA Submission Document Number (if known)
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SECTION A TYPE OF SUBMISSION

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

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name 3M Company, 3M Health Care		Establishment Registration Number (if known) 2110898	
Division Name (if applicable) Medical Division		Phone Number (including area code) (651) 736-2733	
Street Address 3M Center, Building 275-5W-06		FAX Number (including area code) (651)	
City St. Paul	State / Province MN	ZIP/Postal Code 55144-1000	Country USA
Contact Name Maria Ruiz			
Contact Title Senior Regulatory Affairs Associate		Contact E-mail Address mruiz@mmm.com	

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

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

SECTION D1

REASON FOR APPLICATION - PMA, PDP, OR HDE

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

SECTION D2

REASON FOR APPLICATION - IDE

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

SECTION D3

REASON FOR SUBMISSION - 510(k)

<input type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
<input checked="" type="checkbox"/> Other Reason (<i>specify</i>): Addition of viral barrier claim and addition of non-sterile dressings.		

SECTION E

ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	FRO	2		3		4	
		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

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

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

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K063458	1	3M™ Tegaderm™ CHG Dressing	1	3M Company, 3M Health Care
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F

PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Antimicrobial IV Securement Dressings
 Unclassified

Trade or Proprietary or Model Name for This Device

Model Number

1	3M™ Tegaderm™ CHG Dressing	1	1657, 1658, 1659 1657NS, 1658NS, 1659BS
2		2	
3		3	
4		4	
5		5	

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

1	2	3	4	5	6
K063458					
7	8	9	10	11	12

Data Included in Submission

- Laboratory Testing Animal Trials Human Trials

SECTION G

PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

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

Indications (from labeling)

3M™ Tegaderm™ CHG Dressings (Chlorhexidine Gluconate I.V. Securement Dressing), can be used to cover and protect catheter sites and to secure devices to skin. Common applications include IV catheters, other intravascular catheter and percutaneous devices.

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

FDA Document Number (if known)

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

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

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

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

SECTION I

UTILIZATION OF STANDARDS

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

	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2					
3					
4					
5					
6					
7					

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

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

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

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

Section 2

Device Name

Proprietary Name: 3M™ Tegaderm™ CHG Dressing
(Chlorhexidine Gluconate IV Securement Dressing)

Common or Usual Name: Antimicrobial IV Securement Dressing

Classification Name: Antimicrobial Dressing, Unclassified

Performance Standards: None

Section 3

Address and Registration Number

This 510(k) Premarket Notification is submitted by:

3M Health Care
3M Center
Building 275-5W-06
St. Paul, MN 55144-1000
FDA Establishment Registration No. 2110898

Table 1 Manufacturing Information

Catalog Numbers:	Manufacturing	Sterilization
Sterile: 1657 1658 1659	(b)(4)	(b)(4)
Non-sterile: (b)(4)		

Section 4

Device Class

Antimicrobial IV Securement Dressing, Class II (Unclassified)
Product Code: FRO suggested

Section 5

Predicate Device Information

The predicate device is 3M™ Tegaderm™ CHG Dressing, K063458, cleared April 5, 2007.

Draft Labels and Instructions for Use can be found in Attachment 1.

Draft Instructions for Use can be found in Attachment 1. Changes to the Instructions for Use are highlighted in the document. Changes include:

- Addition of viral claim in the description section of the insert.

Addition of the viral claim does not impact packaging. No changes to the content of the packaging have occurred. A representative example of each level of labeling is provided in Attachment 1.

Intended Use

3M™ Tegaderm™ CHG Dressing intended to cover and protect catheter sites and to secure devices to skin. Common applications include IV catheters, other intravascular catheter and percutaneous devices.

No changes to the intended use. This is the same intended use as previously cleared for the 3M™ Tegaderm™ CHG Dressing, 510(k) K063458, April 5, 2008.

Indications for Use Statement

No changes to the Indications for Use Statement have occurred. The Indications for Use statement can be found in Attachment 2.

Section 7

Device Description and Comparison

The device description of 3M™ Tegaderm™ CHG Dressing is as follows:

3M™ Tegaderm™ CHG Dressings are dressings used to cover and protect catheter sites and to secure devices to skin.

Tegaderm™ CHG Dressing consists of a transparent adhesive dressing with a gel pad integrated onto the dressing. The transparent adhesive dressing consists of a thin, polyurethane film backing with a pressure sensitive adhesive. The gel pad is an absorptive gel pad with chlorhexidine gluconate (CHG), a well-known antiseptic agent with broad-spectrum antimicrobial and antifungal activity. ~~The gel pad absorbs fluids, while the CHG incorporated into the gel pad inhibits bacterial growth.~~ The Tegaderm™ CHG dressing is transparent and possesses good moisture vapor permeability and yet is a barrier to liquids, bacteria and viruses. Tegaderm™ CHG Dressings protects the site from outside contamination.

Tegaderm™ CHG Dressings may be provided in two configurations (with border and without border) and in various sizes and shapes to meet the needs of the caregiver. Tegaderm™ CHG Dressings are sold both in sterile (b)(4) Sterile dressings are sold to end-users, (b)(4)

(b)(4)

The only modifications that were made are:

1. Addition of viral barrier. Please see Instructions for Use, Attachment 1 and Attachment 6 for the study report.
2. (b)(4)

(b)(4)

Section 8

Substantial Equivalence

3M™ Tegaderm™ CHG Dressing is composed of the same materials as those used in the 3M™ Tegaderm™ CHG Dressings, cleared under K063458, April 5, 2007.

The tables below illustrate the substantial equivalence to the predicate device. Table 2 provides the similarities and Table 3 provides the modifications.

Table 2 Substantial Equivalence to Predicate - Similarities

Features	Tegaderm™ CHG Dressing Chlorhexidine Gluconate I.V. Securement Dressing (New Device)	Tegaderm™ CHG Dressings Chlorhexidine Gluconate I.V. Securement Dressing (Predicate Device) K063458 Cleared April 5, 2007
Intended Use	No changes. Same intended use as predicate device.	3M™ Tegaderm™ CHG Dressings (Chlorhexidine Gluconate I.V. Securement Dressing), can be used to cover and protect catheter sites and to secure devices to skin.
Indications for Use	No changes. Same indications for use as predicate device.	3M™ Tegaderm™ CHG Dressings (Chlorhexidine Gluconate I.V. Securement Dressing), can be used to cover and protect catheter sites and to secure devices to skin. Common applications include IV catheters, other intravascular catheter and percutaneous devices.
Operating Principle	No change. Same operating principle as predicate device.	Catheter securement device.
Absorbent	No change. Same as predicate device.	Gel pad absorbs fluid.
Transparent	No change. Same as predicate device.	Dressing is transparent.
Breathable	No change. Same as predicate device.	Dressing is breathable.
Secures	No change. Same as predicate device.	Dressing secures devices to skin.
Contains CHG	No change. Same as predicate device.	Gel pad contains 2% w/w CHG
Antimicrobial/ Antifungal	No change. Same as predicate device.	Dressing consists of a transparent adhesive dressing and an integrated gel pad containing CHG, a well-known antiseptic agent with broad spectrum antimicrobial and antifungal activity
Suppresses Regrowth of Micoorganisms	No change. Same as predicate device.	Dressing suppresses re-growth of skin flora of healthy subjects.

Features	Tegaderm™ CHG Dressing Chlorhexidine Gluconate I.V. Securement Dressing (New Device)	Tegaderm™ CHG Dressings Chlorhexidine Gluconate I.V. Securement Dressing (Predicate Device) K063458 Cleared April 5, 2007
Barrier to fluids	No change. Same as predicate device.	The dressing is a barrier to fluids.
Barrier to bacteria	No change. Same as predicate device.	The dressing is a barrier to bacteria.
Barrier to yeast	No change. Same as predicate device.	The dressing is a barrier to yeast.
Materials	No change. Same materials as predicate device.	Composition listed in Table 4 below.
Biocompatibility	No change. Same as predicate device.	The Tegaderm™ CHG dressings were evaluated for biocompatibility with respect to ISO10993-Part 1 <i>Biological Evaluation of Medical Devices</i> for prolonged (24 hours-30 days) skin contact for both patient and/or health care professional exposure. 3M concludes that the Tegaderm™ CHG Dressings would have minimal potential for any adverse health concern and is acceptable for its intended use.
Shelf Life	No change. Same shelf-life as predicate device.	2 years
Sterilization	No change. Same sterilization as predicate device.	Sterile product is ethylene oxide sterilized.

Table 3 Substantial Equivalence to Predicate - Modifications

Features	Tegaderm™ CHG Dressing Chlorhexidine Gluconate I.V. Securement Dressing (New Device)	Tegaderm™ CHG Dressings Chlorhexidine Gluconate I.V. Securement Dressing (Predicate Device) K063458 Cleared April 5, 2007
Barrier to viruses	Addition of viral barrier. See highlighted section in Instructions for Use in Attachment 1. Study Report is provided in Attachment 6.	Not applicable.

Features	Tegaderm™ CHG Dressing Chlorhexidine Gluconate I.V. Securement Dressing (New Device)	Tegaderm™ CHG Dressings Chlorhexidine Gluconate I.V. Securement Dressing (Predicate Device) K063458 Cleared April 5, 2007
Packaging Materials and Processes	Dressings available sterile and non-sterile. (b)(4)	Dressings available sterile.

The only modifications that were made are:

1. Addition of viral barrier. Please see Instructions for Use, Attachment 1. Study Report is provided in Attachment 6.
2. (b)(4)

Table 4 provides the quantitative composition of the gel pad containing CHG of Tegaderm™ CHG Dressings.

(b)(4)

No changes to the composition have been made to the 3M™ Tegaderm™ CIIG Dressings.

Table 5 provides the dimensions of the Tegaderm™ CHG dressing.

Table 5 Product Dimensions

Sterile Tegaderm™ CHG Dressing Size in Centimeters (Inches)	Non-Sterile Tegaderm™ CHG Dressing Size in Centimeters (Inches)	Average amount of CHG per dressing (mg based on gel pad size)
Cat # 1657 8.5 cm x 11.5 cm (3-1/2 x 4-1/2 in)	Cat # 1657NS 8.5 cm x 11.5 cm (3-1/2 x 4-1/2 in)	45
Cat # 1658 10 cm x 12 cm (4 x 4-3/4 in)	Cat # 1658NS 10 cm x 12 cm (4 x 4-3/4 in)	45
Cat # 1659 10 cm x 15.5 cm (4 x 6-1/8 in)	Cat # 1659NS 10 cm x 15.5 cm (4 x 6-1/8 in)	78

(b)(4)

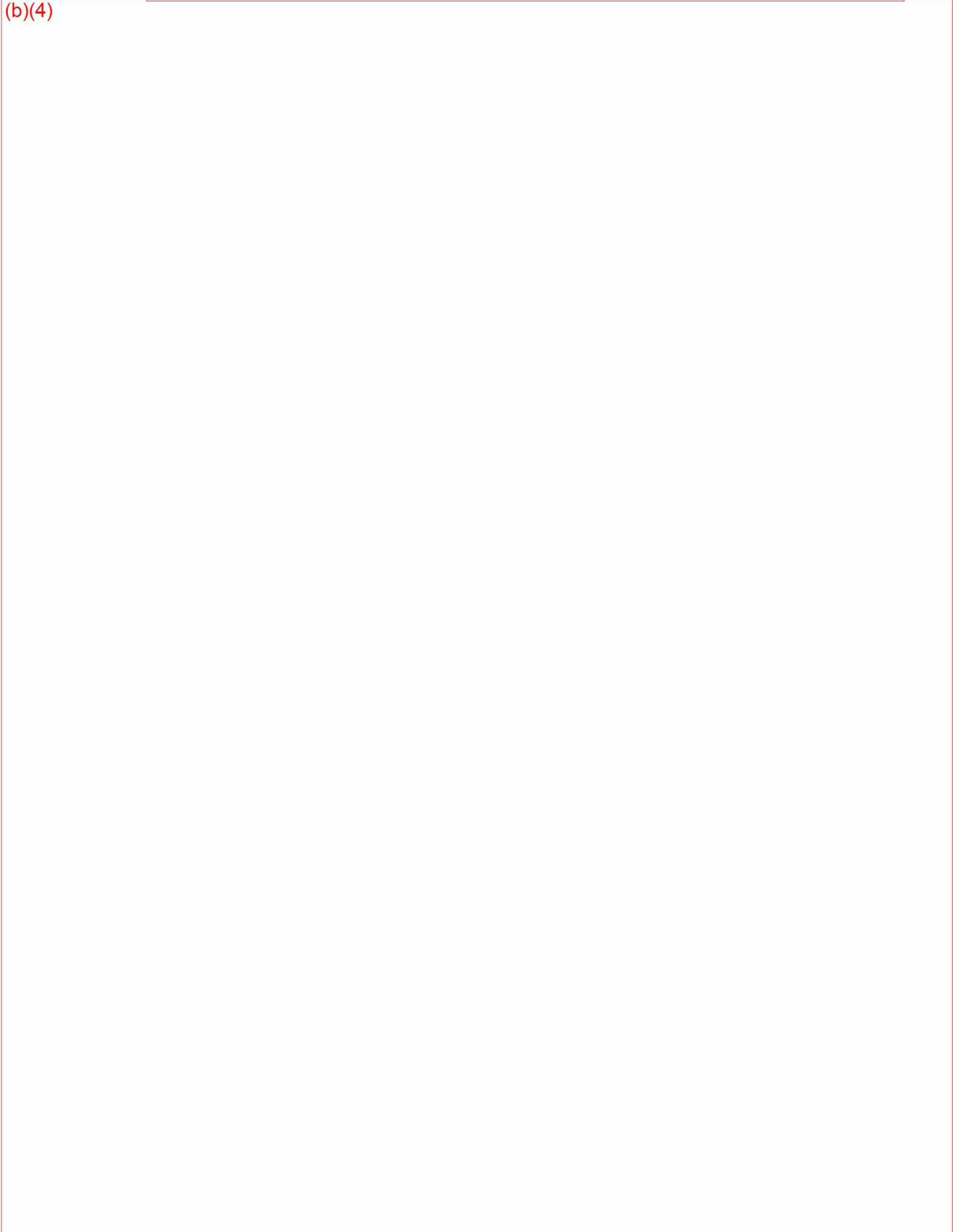
No changes to the amount of CHG per dressing or dimensions of the dressing have occurred. (b)(4) There is no difference in composition or dimensions between sterile dressing (b)(4)

Figure 1 provides a flowchart of the manufacturing process for the Tegaderm™ CHG Dressings.

Figure 1

(b)(4)

(b)(4)



Sterility Assurance Certificate



Sterility Assurance Certification

Tegaderm™ CHG Dressing that are sterilized using ethylene oxide gas are processed using a validated sterilization process. Validation is conducted in accordance with ANSI/AAMI/ISO 11135:1994; Medical devices – Validation and routine control of ethylene oxide sterilization. The validation results in a sterilization process with a Sterility Assurance Level (SAL) of at least 10^{-6} . Product must not contain levels of ethylene oxide (EtO) above the limits stated in ANSI/AAMI/ISO 10993-7 for devices in the category of Prolonged Exposure.

Residual Levels

(b)(4)

Revalidations are conducted on a periodic basis to verify the efficiency of the sterilization process.

Cathy Hill
Cathy Hill, Advanced Microbiologist

29 Feb 2008
Date

These devices will be manufactured by 3M Health Care at the following location:

Catalog Numbers:	Manufacturing	Sterilization
Sterile: 1657 1658 1659	(b)(4)	
(b)(4)		

In summary, the Tegaderm™ CHG Dressing described in this submission is, in our opinion, substantially equivalent to the predicate device.

Section 9

Summary of Design Control Activities

The risk analysis method used to assess the impact of the modifications was a risk assessment complying with ISO 14971:2007 and an assessment on the compatibility of the kit components. The design verification tests that were performed as a result to this risk analysis assessment are listed in Table 7 below.

Table 7 Verification Tests

Modification	Test Performed	Acceptance Criteria
Addition of viral barrier claim	ASTM Method F 1671, Viral Penetration	Negative control sample should be negative for viral penetration. Positive control sample should be positive for viral penetration. The post challenge titer should be $\geq 1.0 \times 10^8$ PFU/mL.
(b)(4)		

The test methods used are the same or equivalent as those identified in the original submission, cleared in K063458, April 5, 2007.

Table 8 Product Methods and Specifications for Testing Tegaderm™ CHG Dressing Stability

Test	3M Method Number	Specification
Chlorhexidine (CHG)	(b)(4)	
para-Chloroaniline (PCA)		
Appearance		

(b)(4) The table has been updated to reflect the current test methods.

A declaration of conformity with design controls is included in Attachment 3.

510(k) Summary

A 510(k) Summary for 3M™ Tegaderm™ CHG Dressing is included in Attachment 4.

Truthful and Accuracy Certification

A certification of the truthfulness and accuracy of the 3M™ Tegaderm™ CHG Dressing described in this submission is provided in Attachment 5.

Attachment 1

Insert and Package Labeling

Insert

Insert

[Modification to the insert is highlighted for ease of review.]

3M™ Tegaderm™ CHG Dressing**Chlorhexidine Gluconate I.V. Securement Dressing****Description:**

3M™ Tegaderm™ CHG Dressing, Chlorhexidine Gluconate IV Securement Dressing, is used to cover and protect catheter sites and to secure devices to skin. Available in a variety of shapes and sizes.

Tegaderm™ CHG Dressing consists of a transparent adhesive dressing and an integrated gel pad containing Chlorhexidine Gluconate (CHG), a well-known antiseptic agent with broad spectrum antimicrobial and antifungal activity. The dressing is a barrier to fluids (waterproof), bacteria, viruses and yeast, and protects the IV site from outside contamination. The gel pad absorbs up to eight times its weight in fluid. *In vitro* testing (log reduction, barrier, and zone of inhibition) demonstrates that the Tegaderm™ CHG dressing has an antimicrobial effect against, and is a barrier to, the passage of a variety of gram-positive and gram-negative bacteria and yeast in the dressing. Tegaderm™ CHG Dressing is transparent, allowing continual site observation, and is breathable, allowing good moisture vapor exchange.

Indications: 3M™ Tegaderm™ CHG Dressing, Chlorhexidine Gluconate I.V. Securement Dressing, can be used to cover and protect catheter sites and to secure devices to skin. Common applications include securing and covering IV catheters, other intravascular catheters and percutaneous devices.

Warning:

DO NOT USE TEGADERM™ CHG DRESSINGS ON PREMATURE INFANTS. USE OF THIS PRODUCT ON PREMATURE INFANTS MAY RESULT IN HYPERSENSITIVITY REACTIONS OR NECROSIS OF THE SKIN. FOR EXTERNAL USE ONLY. DO NOT ALLOW THIS PRODUCT TO CONTACT EARS, EYES, MOUTH OR MUCOUS MEMBRANES.

DO NOT USE THIS PRODUCT ON PATIENTS WITH KNOWN HYPERSENSITIVITY TO CHLORHEXIDINE GLUCONATE. THE USE OF CHLORHEXIDINE GLUCONATE CONTAINING PRODUCTS HAS BEEN REPORTED TO CAUSE IRRITATIONS, SENSITIZATION, AND GENERALIZED ALLERGIC REACTIONS. IF ALLERGIC REACTIONS OCCUR, DISCONTINUE USE IMMEDIATELY, AND IF SEVERE, CONTACT A PHYSICIAN.

Hypersensitivity reactions associated with topical use of Chlorhexidine Gluconate have been reported in several countries. The most serious reactions (including anaphylaxis) have occurred in patients treated with lubricants containing Chlorhexidine Gluconate, which were used during urinary tract procedures. Preparations of this type are not approved for sale in the U.S. under any circumstances. Caution should be used when

using Chlorhexidine Gluconate containing preparations, and the patient should be observed for the possibility of hypersensitivity reactions.

Precautions: 3M™ Tegaderm™ CHG Dressing should not be placed over infected wounds. This device is not intended to treat catheter-related blood stream infections (CRBSI) or other percutaneous device-related infection and has not been studied in a randomized clinical study as to its effectiveness in preventing such infections.

Tegaderm™ CHG dressings should not be re-sterilized by gamma, e-beam or steam methods.

Hemostasis of the catheter site should be achieved before applying the dressing.

Do not stretch the dressing during application. Mechanical skin trauma may result if the dressing is applied with tension.

The skin should be dry and free of detergent residue to prevent skin irritation and to ensure good adhesion.

Instructions for Use:

Dressing Selection: Choose a dressing large enough to provide at least one-inch margin of adherence on dry, healthy skin around the catheter site.

Site Preparation: Prepare the site according to institution protocol. Clipping of hair at the site may improve dressing adhesion. Shaving is not recommended. The skin should be clean, dry and free of detergent residue. Allow all preps and protectants to dry completely before applying the dressing to prevent skin irritation and to ensure good adhesion.

Hemostasis of the catheter site should be achieved before applying the dressing.

Application:

1. Open package and remove sterile dressing.
2. Peel the liner from the dressing, exposing the adhesive surface.
3. Center the gel pad over the catheter site and smooth down dressing edges. Do not stretch dressing during application. Mechanical skin trauma may result if the dressing is applied with tension.
4. Slowly remove the frame while smoothing down the transparent film dressing edges.
5. Smooth the transparent film dressing from the center towards the edges, using firm pressure to enhance adhesion.
6. Document dressing change information according to facility's protocol.

Site Care:

1. The site should be observed daily for signs of infection or other complications. If infection is suspected, remove the dressing, inspect the site directly, and determine

appropriate medical intervention. Infection may be signaled by fever, pain, redness, swelling, or unusual odor or discharge.

2. Change the dressing as necessary, in accordance with facility protocol; dressing changes should occur at a minimum of every 7 days, per current CDC recommendations. Dressing changes may be needed more frequently with highly exudative sites.

Removal: Gently grasp an edge of the transparent dressing and slowly peel the dressing from the skin in the direction of hair growth. Avoid skin trauma by peeling the dressing back, rather than pulling it up from the skin. Alternatively, the dressing can also be removed by grasping an edge of the transparent dressing and gently pull it straight out to stretch it and release adhesion. A medical adhesive solvent can also be used to facilitate dressing removal.

Care should be taken not to dislodge catheters or other devices when the dressing is removed. Support the skin and catheter while removing the dressing.

Shelf Life and Storage Information: For best results, store in a cool, dry place. For shelf life, refer to the expiration date on the package. Sterility of the dressing is guaranteed unless individual package is damaged or open.

Catalog # Dressing Size	Average amount of CHG per dressing (mg based on gel pad size)
Cat # 1657 8.5 cm x 11.5 cm (3-1/2 X 4-1/2 in)	45
Cat # 1658 10 cm X 12 cm (4 X 4-3/4 in)	45
Cat # 1659 10 cm x 15.5 cm (4 X 6-1/8 in)	78

Explanation of Symbols



• Sterile unless package opened or damaged



• This product and package do not contain natural rubber latex

3M Health Care
St. Paul, MN 55144-1000

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3M and Tegaderm are trademarks of 3M.
34-8700-2810-6

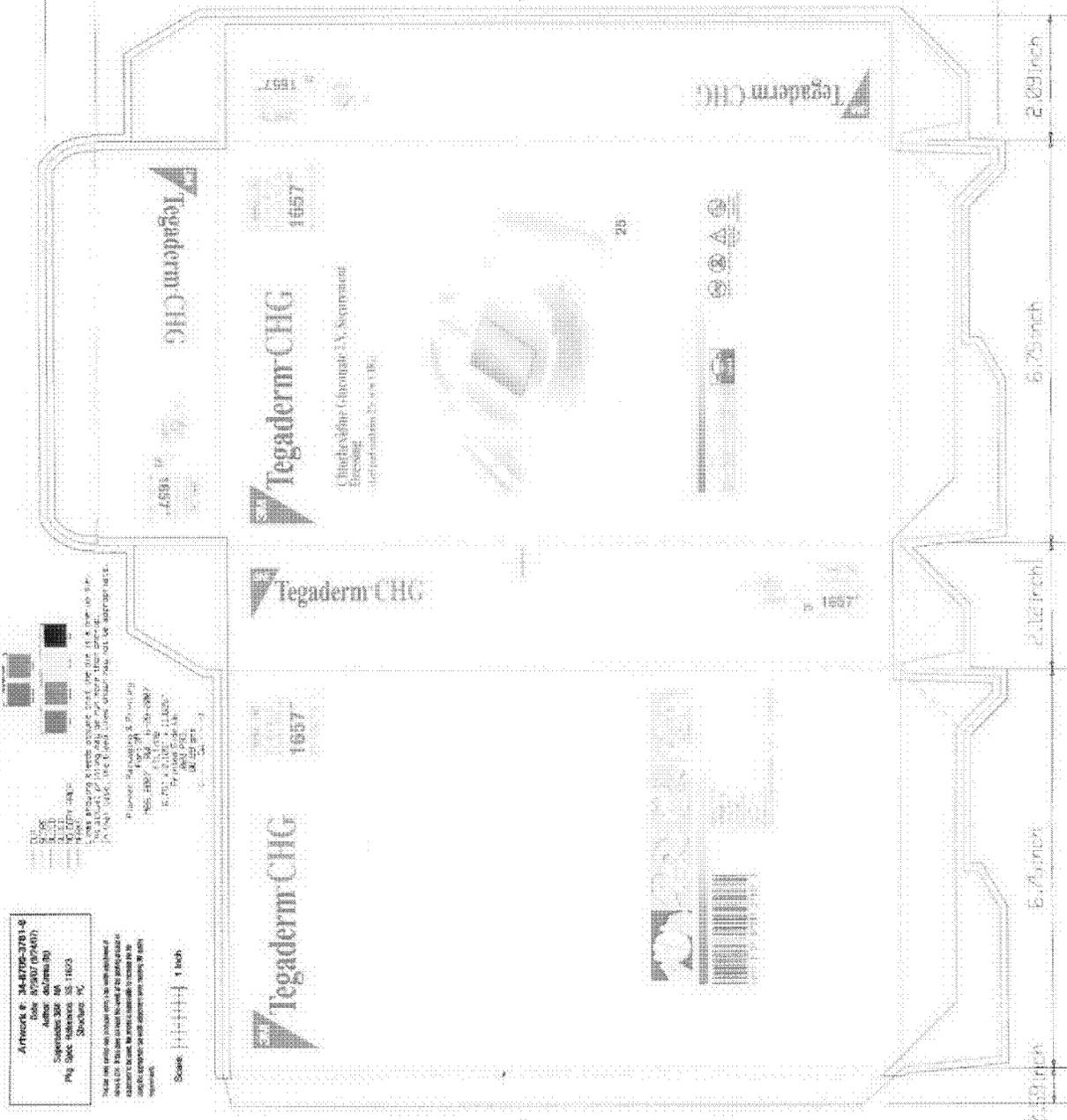
Package Labeling

Article # 34-2705-3761-0
 Title: ACDM (0740)
 Author: dcl/mms (3)
 Supersedes: 300 (4)
 Pkg. Size: 1400
 Pkg. Size: 1400

This set of drawings is provided with the understanding that it is for informational purposes only and is not to be used for construction or other purposes without the express written consent of the author. The author assumes no responsibility for any errors or omissions in these drawings.

Scale: 1 inch = 1 inch

1. All dimensions are in inches unless otherwise noted.
 2. All dimensions are to the centerline unless otherwise noted.
 3. All dimensions are to the finished surface unless otherwise noted.
 4. All dimensions are to the centerline unless otherwise noted.
 5. All dimensions are to the finished surface unless otherwise noted.
 6. All dimensions are to the centerline unless otherwise noted.
 7. All dimensions are to the finished surface unless otherwise noted.
 8. All dimensions are to the centerline unless otherwise noted.
 9. All dimensions are to the finished surface unless otherwise noted.
 10. All dimensions are to the centerline unless otherwise noted.



Approved Artwork
 Date: 10/10/10
 Designer: [Signature]

Indications for Use Statement

510(k) Number (if known): _____

Device Name: 3M™ Tegaderm™ CHG Dressing,
(Chlorhexidine Gluconate I.V. Securement Dressing)

Indications for Use:

3M™ Tegaderm™ CHG Dressings (Chlorhexidine Gluconate I.V. Securement Dressing), can be used to cover and protect catheter sites and to secure devices to skin. Common applications include IV catheters, other intravascular catheter and percutaneous devices.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)

Attachment 3

Declaration of Conformity with Design Controls

Attachment 3 - 1

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Declaration of Conformity with Design Controls

**Verification
Activities**

To the best of my knowledge, the verification activities, as required by the risk analysis, for the modification were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

(b)(4)

*Senior Clinical Research Specialist
3M Health Care*

29 Feb 2008
[Date]

(b)(4)

*Division Scientist
3M Health Care*

29 Feb 2008
[Date]

(b)(4)

*Quality Specialist
3M Health Care*

29 Feb 2008
[Date]

(b)(4)

*Senior Regulatory Affairs Associate
3M Health Care*

29 Feb 2008
[Date]

Declaration of Conformity with Design Controls

**Manufacturing
Facility**

The manufacturing facility, 3M Company, 3M Health Care is in conformance with the design control requirements as specified in 21 CFR 820. 30 and the records are available for review.

(b)(4)

29-Feb-08
[Date]

*Process Development Specialist
3M Health Care*

(b)(4)

2/29/08
[Date]

*Research Specialist
3M Health Care*

(b)(4)

29 FEB 2008
[Date]

*Quality Specialist
3M Health Care*

Attachment 4

510(k) Summary

Attachment 4 - 1

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Premarket Notification (510(k)) Summary

1. Sponsor Information:

3M Health Care
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144-1000

Contact Person: Maria Ruiz
Senior Regulatory Affairs Associate
Phone Number: (651) 736-2733
FAX Number: (651) 737-5320

Date of Summary: March 3, 2008

2. Device Name and Classification:

Common or Usual Name: Antimicrobial I.V. Securement Dressing

Proprietary Name: 3M™ Tegaderm™ CHG Dressing
(Chlorhexidine Gluconate I.V. Securement Dressing)

Classification Name: Antimicrobial Dressing, Unclassified

Performance Standards: None

3. Predicate Devices:

- 3M™ Tegaderm™ CHG Dressings (K063458, cleared April 5, 2007)

4. Description of Device:

3M™ Tegaderm™ CHG Dressing, Chlorhexidine Gluconate I.V. Securement Dressing, is used to cover and protect catheter sites and to secure devices to skin. Available in a variety of shapes and sizes to meet the needs of the caregiver.

Tegaderm™ CHG Dressing consists of a transparent adhesive dressing and an integrated pad containing Chlorhexidine Gluconate (CHG), a well-known antiseptic agent with broad-spectrum antimicrobial and antifungal activity. The dressing is a barrier to liquid (waterproof), bacteria and viruses, and protects the IV site from outside contamination. The pad absorbs up to eight times its weight in fluid and the CHG incorporated into the dressing inhibits bacterial growth.

Tegaderm™ CHG Dressing is transparent, allowing continual site observation, and is breathable, allowing good moisture vapor exchange.

Attachment 5 Truthful and Accuracy Statement

Truthful and Accuracy Statement

Pursuant to 21 CFR 807. 87(j), I *Maria Ruiz*, certify that to the best of my knowledge and belief and based upon the data and information submitted to me in the course of my responsibilities as *Senior Regulatory Affairs Associate* of *3M Company-3M Health Care*, and in reliance thereupon, the data and information submitted in this Premarket notification are truthful and accurate and that no facts material for a review of the substantial equivalence of this device have been knowingly omitted from this submission.

Maria Ruiz
[Signature]

Maria Ruiz
[Typed Name]

29 Feb 2008
[Dated]

Attachment 6

**Viral Penetration
Laboratory Study Report No. (b)(4)**

(b)(4)

FINAL REPORT

VIRAL PENETRATION
ASTM METHOD F 1671

(b)(4)

PREPARED FOR:

(b)(4)

SUBMITTED BY:

(b)(4)



COVER SHEET MEMORANDUM

From: Reviewer Name Suzanne Magli
 Subject: 510(k) Number K080620/S1
 To: The Record May 15, 2008

Please list CTS decision code SE

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/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	<input checked="" type="checkbox"/>	
510(k) Summary / 510(k) Statement	Attach Summary	<input checked="" type="checkbox"/>	
Truthful and Accurate Statement.	Must be present for a Final Decision	<input checked="" type="checkbox"/>	
Is the device Class III?			
If yes, does firm include Class III Summary?	Must be present for a Final Decision		<input checked="" type="checkbox"/>
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			<input checked="" type="checkbox"/>
Is this a combination product? (Please specify category <u>4</u> , see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)		<input checked="" type="checkbox"/>	
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)			<input checked="" type="checkbox"/>
Is this device intended for pediatric use only?			<input checked="" type="checkbox"/>
Is this a prescription device? (If both prescription & OTC, check both boxes.)		<input checked="" type="checkbox"/>	
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, <i>Certification with Requirements of Clinical Trials.gov Data Bank</i> ? (If not, then applicant must be contacted to obtain completed form.)			<input checked="" type="checkbox"/>
Does this device include an Animal Tissue Source?			<input checked="" type="checkbox"/>
All Pediatric Patients age <= 21			<input checked="" type="checkbox"/>
Neonate/Newborn (Birth to 28 days)			<input checked="" type="checkbox"/>
Infant (29 days - < 2 years old)			<input checked="" type="checkbox"/>
Child (2 years - < 12 years old)			<input checked="" type="checkbox"/>
Adolescent (12 years - < 18 years old)			<input checked="" type="checkbox"/>
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.)			<input checked="" type="checkbox"/>
Transitional Adolescent B (18 - <= 21; No special considerations compared to adults => 21 years old)			<input checked="" type="checkbox"/>
Nanotechnology			<input checked="" type="checkbox"/>

Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	Contact OSB.	<input checked="" type="checkbox"/>
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.	<input checked="" type="checkbox"/>

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

Additional Product Codes:

Review: David X. Name PRSB May 16, 2008
(Branch Chief) (Branch Code) (Date)

Final Review: Michael J. ... 5/19/08
(Division Director) (Date)

**Special 510(K) Review
K080620/S001**

Date: May 15, 2008

To: The Record

From: Suzanne Malli

Office/Division/Branch: ODE/DGRD/PRSB, HFZ-410

Device Name: Tegaderm CHG Securement Dressing

Company Name: 3M

**Contact: 3M Company
3M Health Care
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144
Maria Ruiz
(651)-736-2733 Office
(651)-737-5320 FAX**

I. Background

1. The name and 510(k) number of previously cleared device.

K063458 3M Tegaderm CHG Dressing cleared 4/05/2007

Additionally, the following devices have been cleared with viral barrier claims:
K895207, K895353, K973036, K080524

The following statement is found in the K080524 (cleared 4/23/2008

SorbaView® dressings were also tested for viral and blood barrier effectiveness in accordance with ASTM F 1671-97b and 107098, respectively, and found to be effective against penetration of both viral and blood contaminants.

This statement appears in the product labeling:

“The test results show that SorbaView Ultimate dressings are resistant to viral penetration and behave as viral barriers. The tested Phi-X 174 bacteriophage is one of the smallest known viruses. Therefore, by inference the test provides indirect evidence to suggest that SorbaView Ultimate dressings would behave as a barrier to other larger viral and bacterial contaminants.”

2. 3M provided a statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use and package labeling.

“3M Tegaderm Transparent Dressings can be used to cover and protect catheters sites and to secure devices to the skin. Common applications include: IV catheters other intravascular catheters and percutaneous devices.”

3. 3M provided a description of the device **MODIFICATIONS**, in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device has not changed.

A. DESCRIPTION OF THE DEVICE MODIFICATION:

Adding a viral barrier claim to their labeling. (b)(4)

(b)(4)

(b)(4)

The sole purpose of this submission is to obtain the viral barrier claim.

B. COMPARISON INFORMATION TO LEGALLY MARKETED PREDICATE DEVICE:

The company provided comparison information to their legally marketed predicate device (K03458) including, labeling, intended use, physical characteristics, substantial equivalence comparison table of the subject and predicate device in terms of materials, physical, labeling, and intended uses.

The device is not life-supporting or life-sustaining, and the device is not considered an implant. The device does not contain software. The device components are provided as single-use. The device is sold by prescription only.

Tegaderm CHG Antimicrobial Securement Dressing:

A hydrogel pad containing Chlorhexidine Gluconate (CHG) integrated with a transparent adhesive dressing. This dressing was cleared in K063458. The integrated product (Tegaderm CHG Securement Dressing) consists of a transparent adhesive dressing with the hydrogel pad containing CHG integrated into the center of the dressing. The transparent adhesive dressing consists of a film and a water-resistant pressure sensitive acrylate adhesive. The device may be provided in different configurations and sizes and thicknesses.

The composition of this dressing is the following (the percentages are by weight):

- (b)(4)

-
-
-
-
-

7

7

II. ADMINISTRATIVE REQUIREMENTS:

- A. INDICATIONS FOR USE FORM:** page 2-2
- B. TRUTHFUL AND ACCURACY STATEMENT:** page 5-2
- C. 510(K) SUMMARY OR STATEMENT:** page 4-2
- D. FDA ESTABLISHMENT REGISTRATION NUMBER:** 2110898

III. DESIGN CONTROL ACTIVITIES SUMMARY:

- A. RISK ANALYSIS METHOD(S):** The company provided an acceptable risk analysis.
- B. VALIDATION ACTIVITIES UNDERTAKEN TO SUPPORT CHANGE:**

The company submitted a viral penetration study to support their claim of “barrier to viruses”. The testing was completed in conformance with ASTM F 1671-07 and the testing virus was bacteriophage Phi X-174. The testing tested (b)(4) Bacteriophage are not small enough to cover all known viruses. Therefore, the testing is not sufficient for a claim for all viruses. A deficiency was sent for the company to do testing demonstrating that model viruses small enough in size to support a claim that if small viruses are unable to penetrate the dressing therefore, larger viruses will also not be able to penetrate the dressing. The company responded by modifying their claim to state the size of viruses tested was 27nm and therefore Tegaderm CHG provides a barrier to viruses larger than 27nm (e.g., HBV, HCV and HIV). This claim is acceptable and is similar to claims made by the predicate devices.

- C. DECLARATION OF CONFORMITY WITH DESIGN CONTROLS:**

The following was provided by the company:

1. A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individuals and the results demonstrated that the predetermined acceptance criteria were met, and
2. A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

IV. LABELING:

The labeling for this modified device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification.

V. Deficiencies from Initial submission sent to the company April 10, 2008:

- 1. You submitted a device description that includes the following claim, "CHG incorporated into the gel pad inhibits bacterial growth". Please be advised that performance claims should be supported with data. The text of the labeling claims should be data-driven and limited to the summary of the testing methods and results obtained. It is expected that for antibacterial claims the claim will be the data demonstrating that the wound dressing has an antibacterial effect against tested microorganisms in vitro, and the wound dressing is a barrier to the passage of the specific microorganisms tested. The statement, "CHG incorporated into the gel pad inhibits bacterial growth" does not follow these guidelines, therefore, it is not acceptable. You agreed in K063458 to remove "CHG incorporated into the gel pad inhibits bacterial growth" and replace it with *"In vitro testing (log reduction, barrier, and zone of inhibition) demonstrates that the Tegaderm™ CHG dressing has an antimicrobial effect against, and is a barrier to, the passage of a variety of gram-positive and gram-negative bacteria and yeast."* Please revise this claim and any other similar claims, so that they follow these guidelines.**

The company responded that the claim "CHG incorporated into the gel pad inhibits bacterial growth" was changed to *"In vitro testing (log reduction, barrier, and zone of inhibition) demonstrates that the Tegaderm™ CHG dressing has an antimicrobial effect against, and is a barrier to, the passage of a variety of gram-positive and gram-negative bacteria and yeast."* This was an acceptable response.

- 2. You submitted viral penetration testing on bacteriophage in support of your claim that the subject device acts as a barrier to viruses. The data you submitted is not sufficient to demonstrate that the subject device is a barrier to all viruses. Please submit viral testing using model viruses which are small enough in size to demonstrate that various larger viruses will not penetrate the device. Additionally, please submit a predicate device for which the subject device will be substantially equivalent with regard to a wound dressing acting as a viral barrier. In the absence of a predicate device, please provide clinical data to support this claim.**

The company responded with at least four predicates that had the viral claim in their labeling. Specifically K080524 had the viral barrier claim for testing completed according to ASTM F 1671. The company also modified their labeling to state that a 27nm bacteriophage was tested to demonstrate the Tegaderm's ability to act as a barrier to viruses larger than 27nm such as HIV, HCV and HBV. This was an acceptable response.

3. You have stated that you (b)(4) Tegaderm
CHG (b)(4)

(b)(4)

(b)(4) Tegaderm CHG was cleared as an individually sterilized device. (b)(4)

(b)(4)

(b)(4)

4. Your Special 510(k) does not include a Design Control Activities Summary (DCAS). An adequate Design Control Activities Summary is an essential part of a Special 510(k) submission. Therefore, please provide a DCAS which identifies specific information on the device modifications, all risks which result from these changes, verification activities, and specific (quantitative) acceptance criteria, and results of verification. To elaborate, the DCAS should address potential risks due to the noted changes. Any relevant changes in the manufacturing process, including the sterilization method, should be considered as well. See attachment for further explanation of the Design Control Activities Summary.

The company provided an acceptable risk analysis based on the addition of the viral claim to their labeling. This was an acceptable response.

5. Please provide a revised Truthful and Accuracy statement that correctly states “as required by 21 CFR 807.87 (k)” not 21 CFR 807.87 (j).

The company provided an updated Truthful and Accuracy statement but they did not date the document. Therefore, a dated version will be requested.

VI. SPONSOR CONTACTS:

The company was notified by email that the viral barrier is based on the pore size of the Tegaderm wound dressing and the CHG does have any affect on the viral barrier claim.

VII. RECOMMENDATION: Substantially Equivalent

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter’s description of the particular modification and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has

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provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared device.



05/15/08

Name

Suzanne Malli

(Date)

Division of General, Restorative & Neurological Devices
Plastic & Reconstructive Surgery Branch

I concur,
Daniel Krane
May 15, 2008

Malli, Suzanne M

m: Malli, Suzanne M
nt: Tuesday, May 13, 2008 10:41 AM
To: 'meruiz@mmm.com'
Subject: RE: K080620

Maria,

The document is under review. I will let you know when the review is completed.

Thank you,

Suzanne Malli

From: meruiz@mmm.com [mailto:meruiz@mmm.com]
Sent: Monday, May 12, 2008 5:00 PM
To: Malli, Suzanne M
Subject: Re: K080620

Dear Suzanne,

I have tried to reach you by telephone and have left a message on your voicemail. I was calling in regards to 3M's application K080620, Tegaderm CHG Dressing, Special 510(k). What is the status of the application? Has the review been completed?

Please let me know if you have any questions. Thanks, Maria

Kind Regards,
Maria Ruiz, RAC-US
Senior Regulatory Affairs Associate
3M Medical Division, Regulatory Affairs
3M Center, Bldg 275-5W-06
St. Paul, MN 55144-1000
Tel: 651-736-2733
Fax: 651-737-5320
email: meruiz@mmm.com

This communication contains confidential information. If you are not the intended recipient please return this email to the sender and delete it from your records.

Malli, Suzanne M

m: Malli, Suzanne M
nt: Tuesday, April 22, 2008 1:16 PM
To: 'meruiz@mmm.com'
Subject: K08620

Maria,

I have tried to reach by telephone but your line has been busy. What is your question?

Suzanne Malli
Plastic and Reconstructive Surgery Devices Branch
Division of General, Restorative, and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health
U.S. Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850
240.276.3621 office
240.276.3733 fax
suzanne.malli@fda.hhs.gov

Malli, Suzanne M

From: Malli, Suzanne M
Sent: Thursday, May 15, 2008 12:17 PM
To: 'meruiz@mmm.com'
Subject: K080620

Dear Maria,

I am ready to make my recommendation regarding K080620, however, I have a few issues remaining to resolve:

- 1) Please be advised that the viral barrier claim is due to the effect of the dressing and the viral barrier claim should not be made with any reference to the Chlorhexidine present in the dressing.
- 2) Please revise your statement in the labeling to read something to this affect, "*In vitro* testing shows that Tegaderm CHG provides a viral barrier from viruses 27nm in diameter (e.g. HCV) or larger (e.g. HCV or HIV) while the dressing remains intact without leakage." The "has proven" phrase is what needs to be modified.
- 3) The Truthful and Accuracy statement you updated is signed but does not include the date. Please update this statement to include a signature with a date.

Thank you,

Suzanne Malli
Plastic and Reconstructive Surgery Devices Branch
Division of General, Restorative, and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health
U.S. Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850
240.276.3621 office
240.276.3733 fax
suzanne.malli@fda.hhs.gov

PRE-REVIEW FORM: COMPANY/DEVICE HISTORY

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

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

Special 510(K) Review
K080620

Date: April 8, 2008

To: The Record

From: Suzanne Malli

Office/Division/Branch: ODE/DGRD/PRSB, HFZ-410

Device Name: Tegaderm CHG Securement Dressing

Company Name: 3M

Contact: 3M Company
3M Health Care
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144
Maria Ruiz
(651)-736-2733 Office
(651)-737-5320 FAX

I. Background

1. The name and 510(k) number of previously cleared device.

K063458 3M Tegaderm CHG Dressing cleared 4/05/2007

2. 3M provided a statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use and package labeling.

“3M Tegaderm Transparent Dressings can be used to cover and protect catheters sites and to secure devices to the skin. Common applications include: IV catheters other intravascular catheters and percutaneous devices.”

3. 3M provided a description of the device **MODIFICATIONS**, in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device has not changed.

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A. DESCRIPTION OF THE DEVICE MODIFICATION:

Adding viral barrier claim (b)(4)
(b)(4)

B. COMPARISON INFORMATION TO LEGALLY MARKETED PREDICATE DEVICE:

The company provided comparison information to their legally marketed predicate device (K063456) including, labeling, intended use, physical characteristics, substantial equivalence comparison table of the subject and predicate device in terms of materials, physical, labeling, and intended uses.

The device is not life-supporting or life-sustaining, but the device is not considered an implant. The device does not contain software. The device components are provided ~~pre~~ single-use. The device is sold by prescription only.

Tegaderm CHG Antimicrobial Securement Dressing:
A hydrogel pad containing Chlorohexidine Gluconate (CHG) integrated with a transparent adhesive dressing

The device may be provided in different configurations and sizes and thicknesses.

The composition of this dressing is the following (the percentages are by weight):

- (b)(4)
-
-
-
-

The integrated product (Tegaderm CHG Securement Dressing) consists of a transparent adhesive dressing with the hydrogel pad containing CHG integrated into the center of the dressing. The transparent adhesive dressing consists of a film and a water-resistant pressure sensitive acrylate adhesive.

II. ADMINISTRATIVE REQUIREMENTS:

A. INDICATIONS FOR USE FORM: page 2-2

B. TRUTHFUL AND ACCURACY STATEMENT: page 5-2

C. 510(K) SUMMARY OR STATEMENT: page 4-2

D. FDA ESTABLISHMENT REGISTRATION NUMBER: 2110898

III. DESIGN CONTROL ACTIVITIES SUMMARY:

A. RISK ANALYSIS METHOD(S): None provided; will be requested.

B. VALIDATION ACTIVITIES UNDERTAKEN TO SUPPORT CHANGE:

The company stated this was done but the risk analysis is not adequate, therefore, a deficiency will be sent to the company.

The company submitted a viral penetration study to support their claim of “barrier to viruses”. The testing utilized bacteriophage. Bacteriophage are not not small enough to cover all known viruses. Therefore, the testing is not sufficient for this claim. A deficiency will be sent for the company to do testing demonstrating that model viruses small enough in size to support a claim that if small viruses are unable to penetrate the dressing therefore, larger viruses will also not be able to penetrate the dressing. At this time the company has not shown this to be true. Also, the company has not provided a predicate device with such a claim. A predicate will be requested and if absence of a predicate clinical data will be requested.

C. DECLARATION OF CONFORMITY WITH DESIGN CONTROLS:

1. A signed statement was provided.
2. A signed statement was provided that the Design Control Procedure Requirements as Specified in 21 CFR 820.30 and that the Records are Available for Review.

IV. LABELING:

The labeling for this modified device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification.

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IV. SPONSOR CONTACTS:

V. RECOMMENDATION:

Additional information is required to make a substantial equivalence determination. Therefore, an AI letter will be sent to the company.

David Krone for April 8, 2008
Name *(Date)*
Suzanne Malli
Division of General, Restorative & Neurological Devices
Plastic & Reconstructive Surgery Branch

I concur

David Krone
4/8/2008

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

April 22, 2008

3M COMPANY-3M HEALTH CARE
MEDICAL DIVISION
3M CENTER, BLDG. 275-5W-06
ST. PAUL, MN 55144
ATTN: MARIA RUIZ

510(k) Number: K080620
Product: MODIFICATION TO
3M TEGADERM CHG
DRESSING

The additional information you have submitted has been received.

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

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

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

Sincerely yours,

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

K080620 / 51



Special 510(k): Device Modification - Response

April 18, 2008

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

**Reference : K080620, 3M™ Tegaderm™ CHG Dressing
Chlorhexidine Gluconate I.V. Securement Dressing
Response to April 10, 2008 FDA Correspondence**

Dear Madam/Sir:

3M submits this response to FDA's correspondence dated April 10, 2008 requesting additional information regarding 3M's Special 510(k) Premarket Notification (K080620) for the 3M™ Tegaderm™ CHG Dressing (Chlorhexidine Gluconate I.V. Securement Dressing). This submission is provided to supplement 3M's 510(k) filing and is submitted in duplicate.

3M considers the information provided under this submission to be a trade secret and confidential commercial information under 21 CFR 20.61 and requests that the Food and Drug Administration no disclose this information either in response to a Freedom in Information Request or by any other means.

If you have any questions regarding this response, please contact me using the information provided below.

Sincerely,

Maria Ruiz
Senior Regulatory Affairs Associate
3M Health Care, Medical Division
3M Center, Bldg 275-5W-06
St. Paul, MN 55144-1000
Phone: (651) 736-2733
Fax: (651) 737-5320
meruiz@mmm.com

FDA CDRH DMC

APR 22 2008

Received

10 5 16

Response to FDA Correspondence Dated April 10, 2008
Re: K080620, Tegaderm™ CHG Dressing

The FDA's comments from FDA correspondence dated April 10, 2008 are provided below in bold text followed by 3M's response.

- 1. You submitted a device description that includes the following claim, "CHG incorporated into the gel pad inhibits bacterial growth". Please be advised that performance claims should be supported with data. The text of the labeling claims should be data-driven and limited to the summary of the testing methods and results obtained. It is expected that for antibacterial claims the claim will be supported by data demonstrating that the wound dressing has an antibacterial effect against tested microorganisms in vitro, and the wound dressing is a barrier to the passage of the specific microorganisms tested. The statement, "CHG incorporated into the gel pad inhibits bacterial growth" does not follow these guidelines, therefore, it is not acceptable. You agreed in K063458 to remove "*CHG incorporated into the gel pad inhibits bacterial growth*" and replace it with "*In vitro testing (log reduction, barrier, and zone of inhibition) demonstrates that the Tegaderm™ CHG dressing has an antimicrobial effect against, and is a barrier to, the passage of a variety of gram-positive and gram-negative bacteria and yeast.*" Please revise this claim and any other similar claims, so that they follow these guidelines.**

3M Response:

The bacterial claim in the insert follows the guideline outlined above. This language was cleared April 5, 2007 (K063458). The language in the Device Description section will be revised to follow the guideline as follows and match the insert:

"In vitro testing (log reduction, barrier, and zone of inhibition) demonstrates that the Tegaderm™ CHG dressing has an antimicrobial effect against, and is a barrier to, the passage of a variety of gram-positive and gram-negative bacteria and yeast."

An updated Summary Statement is provided in Attachment 6.

- 2. You submitted penetration testing on bacteriophage in support of your claim that the subject device acts as a barrier to viruses. The data you submitted is not sufficient to demonstrate that the subject device is a barrier to all viruses. Please submit viral testing using model viruses which are small enough in size to demonstrate that various larger viruses will not penetrate the device. Additionally, please submit a predicate device for which the subject device will be substantially equivalent with regard to a wound dressing acting as a viral barrier. In the absence of a predicate device, please provide clinical data to support this claim.**

3M Response:

Viral penetration testing using ASTM Method F 1671 was performed to support the viral claim for the Tegaderm CHG Dressing. ASTM Method F 1671 is commonly used for viral barrier testing for transparent dressings.

ASTM F 1671 has been specifically designed for measuring penetration of a surrogate microbe for Hepatitis (B and C) and Human Immunodeficiency Viruses. The surrogate, Phi-X174 Bacteriophage, used in this test method is similar to HCV in size (27 nm) and shape but also serves as a surrogate for HBV and HIV [See Attachment 4 for a copy of the method.].

The viral claim will be updated to only include those viruses for which the method and results are applicable:

**In vitro* testing has proven that Tegaderm CHG provides a viral barrier from viruses 27 nm in diameter, (e.g. HCV) or larger (e.g. HBV and HIV) while the dressing remains intact without leakage.

An updated insert is provided in Attachment 1.

The predicate devices for the viral barrier claim are as follows:

- Bioclusive Transparent Film Dressing (K895207, cleared September 28, 1989)
- Opsite IV 3000 (K895353, cleared December 14, 1989)
- Tegaderm™ Transparent Film Dressings (K973036, cleared November 12, 1997)
- SorbaView® Ultimate Window Dressing
- SorbaView® 2000

Copies of the viral claim for the predicate devices are provided in Attachment 5.

3. You have stated that you (b)(4) Tegaderm CHG (b)(4) Tegaderm CHG (b)(4) (b)(4) (b)(4) Tegaderm CHG was cleared as an individually sterilized device. (b)(4) (b)(4) (b)(4)

3M Response:

(b)(4)

4. Your special 510(k) does not include a Design Control Activities Summary (DCAS). An adequate Design Control Activities Summary is an essential part of a Special 510(k) submission. Therefore, please provide a DCAS which

identifies specific information on the design modifications, all risks which result from these changes, verification activities, and specific (quantitative) acceptance criteria, and results of verification. To elaborate, the DCAS should address potential risks due to the noted changes. Any relevant changes in the manufacturing process, including the sterilization method, should be considered as well. See attachment for further explanation of the Design Control Activities Summary.

3M Response:

A Design Control Activities Summary (DCAS) for the modifications is provided in Attachment 2.

- 5. Please provide a revised Truthful and Accuracy statement that correctly states "as required by 21 CFR 807.87 (k)" not 21 CFR 807.87 (j).**

3M Response:

The Truthful and Accuracy statement has been updated. A corrected statement is provided in Attachment 3.

Attachment 1
Draft Product Insert

Insert

[Modification to the insert is highlighted for ease of review.]

3M™ Tegaderm™ CHG Dressing

Chlorhexidine Gluconate I.V. Securement Dressing

Description:

3M™ Tegaderm™ CHG Dressing, Chlorhexidine Gluconate IV Securement Dressing, is used to cover and protect catheter sites and to secure devices to skin. Available in a variety of shapes and sizes.

Tegaderm™ CHG Dressing consists of a transparent adhesive dressing and an integrated gel pad containing Chlorhexidine Gluconate (CHG), a well-known antiseptic agent with broad spectrum antimicrobial and antifungal activity. The dressing is a barrier to fluids (waterproof), bacteria, viruses* and yeast, and protects the IV site from outside contamination. The gel pad absorbs up to eight times its weight in fluid. *In vitro* testing (log reduction, barrier, and zone of inhibition) demonstrates that the Tegaderm™ CHG dressing has an antimicrobial effect against, and is a barrier to, the passage of a variety of gram-positive and gram-negative bacteria and yeast in the dressing. Tegaderm™ CHG Dressing is transparent, allowing continual site observation, and is breathable, allowing good moisture vapor exchange.

**In vitro* testing has proven that Tegaderm CHG provides a viral barrier from viruses 27 nm in diameter, (e.g. HCV) or larger (e.g. HBV and HIV) while the dressing remains intact without leakage.

Indications: 3M™ Tegaderm™ CHG Dressing, Chlorhexidine Gluconate I.V. Securement Dressing, can be used to cover and protect catheter sites and to secure devices to skin. Common applications include securing and covering IV catheters, other intravascular catheters and percutaneous devices.

Warning:

DO NOT USE TEGADERM™ CHG DRESSINGS ON PREMATURE INFANTS. USE OF THIS PRODUCT ON PREMATURE INFANTS MAY RESULT IN HYPERSENSITIVITY REACTIONS OR NECROSIS OF THE SKIN. FOR EXTERNAL USE ONLY. DO NOT ALLOW THIS PRODUCT TO CONTACT EARS, EYES, MOUTH OR MUCOUS MEMBRANES.

DO NOT USE THIS PRODUCT ON PATIENTS WITH KNOWN HYPERSENSITIVITY TO CHLORHEXIDINE GLUCONATE. THE USE OF CHLORHEXIDINE GLUCONATE CONTAINING PRODUCTS HAS BEEN REPORTED TO CAUSE IRRITATIONS, SENSITIZATION, AND GENERALIZED ALLERGIC REACTIONS. IF ALLERGIC REACTIONS OCCUR, DISCONTINUE USE IMMEDIATELY, AND IF SEVERE, CONTACT A PHYSICIAN.

Hypersensitivity reactions associated with topical use of Chlorhexidine Gluconate have been reported in several countries. The most serious reactions (including anaphylaxis)

have occurred in patients treated with lubricants containing Chlorhexidine Gluconate, which were used during urinary tract procedures. Preparations of this type are not approved for sale in the U.S. under any circumstances. Caution should be used when using Chlorhexidine Gluconate containing preparations, and the patient should be observed for the possibility of hypersensitivity reactions.

Precautions: 3M™ Tegaderm™ CHG Dressing should not be placed over infected wounds. This device is not intended to treat catheter-related blood stream infections (CRBSI) or other percutaneous device-related infection and has not been studied in a randomized clinical study as to its effectiveness in preventing such infections.

Tegaderm™ CHG dressings should not be re-sterilized by gamma, e-beam or steam methods.

Hemostasis of the catheter site should be achieved before applying the dressing.

Do not stretch the dressing during application. Mechanical skin trauma may result if the dressing is applied with tension.

The skin should be dry and free of detergent residue to prevent skin irritation and to ensure good adhesion.

Instructions for Use:

Dressing Selection: Choose a dressing large enough to provide at least one-inch margin of adherence on dry, healthy skin around the catheter site.

Site Preparation: Prepare the site according to institution protocol. Clipping of hair at the site may improve dressing adhesion. Shaving is not recommended. The skin should be clean, dry and free of detergent residue. Allow all preps and protectants to dry completely before applying the dressing to prevent skin irritation and to ensure good adhesion.

Hemostasis of the catheter site should be achieved before applying the dressing.

Application:

1. Open package and remove sterile dressing.
2. Peel the liner from the dressing, exposing the adhesive surface.
3. Center the gel pad over the catheter site and smooth down dressing edges. Do not stretch dressing during application. Mechanical skin trauma may result if the dressing is applied with tension.
4. Slowly remove the frame while smoothing down the transparent film dressing edges.
5. Smooth the transparent film dressing from the center towards the edges, using firm pressure to enhance adhesion.
6. Document dressing change information according to facility's protocol.

Site Care:

1. The site should be observed daily for signs of infection or other complications. If infection is suspected, remove the dressing, inspect the site directly, and determine appropriate medical intervention. Infection may be signaled by fever, pain, redness, swelling, or unusual odor or discharge.
2. Change the dressing as necessary, in accordance with facility protocol; dressing changes should occur at a minimum of every 7 days, per current CDC recommendations. Dressing changes may be needed more frequently with highly exudative sites.

Removal: Gently grasp an edge of the transparent dressing and slowly peel the dressing from the skin in the direction of hair growth. Avoid skin trauma by peeling the dressing back, rather than pulling it up from the skin. Alternatively, the dressing can also be removed by grasping an edge of the transparent dressing and gently pull it straight out to stretch it and release adhesion. A medical adhesive solvent can also be used to facilitate dressing removal.

Care should be taken not to dislodge catheters or other devices when the dressing is removed. Support the skin and catheter while removing the dressing.

Shelf Life and Storage Information: For best results, store in a cool, dry place. For shelf life, refer to the expiration date on the package. Sterility of the dressing is guaranteed unless individual package is damaged or open.

Catalog # Dressing Size	Average amount of CHG per dressing (mg based on gel pad size)
Cat # 1657 8.5 cm x 11.5 cm (3-1/2 X 4-1/2 in)	45
Cat # 1658 10 cm X 12 cm (4 X 4-3/4 in)	45
Cat # 1659 10 cm x 15.5 cm (4 X 6-1/8 in)	78

Explanation of Symbols



• Sterile unless package opened or damaged



• This product and package do not contain natural rubber latex

3M Health Care
St. Paul, MN 55144-1000

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34-8700-2810-6

Attachment 2

Design Control Activities Summary (DCAS)

Design Control Activities Summary for Tegaderm™ CHG Dressing

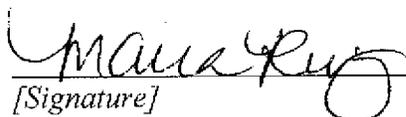
Device Modification	Risk	Verification Activity	Acceptance Criteria	Results of Verification
Addition of viral barrier.	No changes made to the device, indications for use, or intended use. Additional testing was done to verify barrier performance. This test was done to add a promotional claim.	ASTM Method F 1671, Viral Penetration		(b)(4)

Attachment 3

Truthful and Accuracy Statement

Truthful and Accuracy Statement

Pursuant to 21 CFR 807.87(k), I, *Maria Ruiz*, certify that to the best of my knowledge and belief and based upon the data and information submitted to me in the course of my responsibilities as *Senior Regulatory Affairs Associate* of *3M Company, 3M Health Care*, and in reliance thereupon, the data and information submitted in this Premarket notification are truthful and accurate and that no facts material for a review of the substantial equivalence of this device have been knowingly omitted from this submission.



[Signature]

Maria Ruiz

[Typed Name]

Attachment 4

ASTM (b)(4)

Attachment 5

Predicate Devices for Viral Barrier

HOME REGISTER LOGIN HELP PRIVACY POLICY

Johnson & Johnson
GATEWAY®



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More Information

[BIOCLUSIVE Select Transparent Dressing and BIOCLUSIVE Transparent Dressing](#)

Microsite

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- [Advanced Wound Care Reimbursement](#)

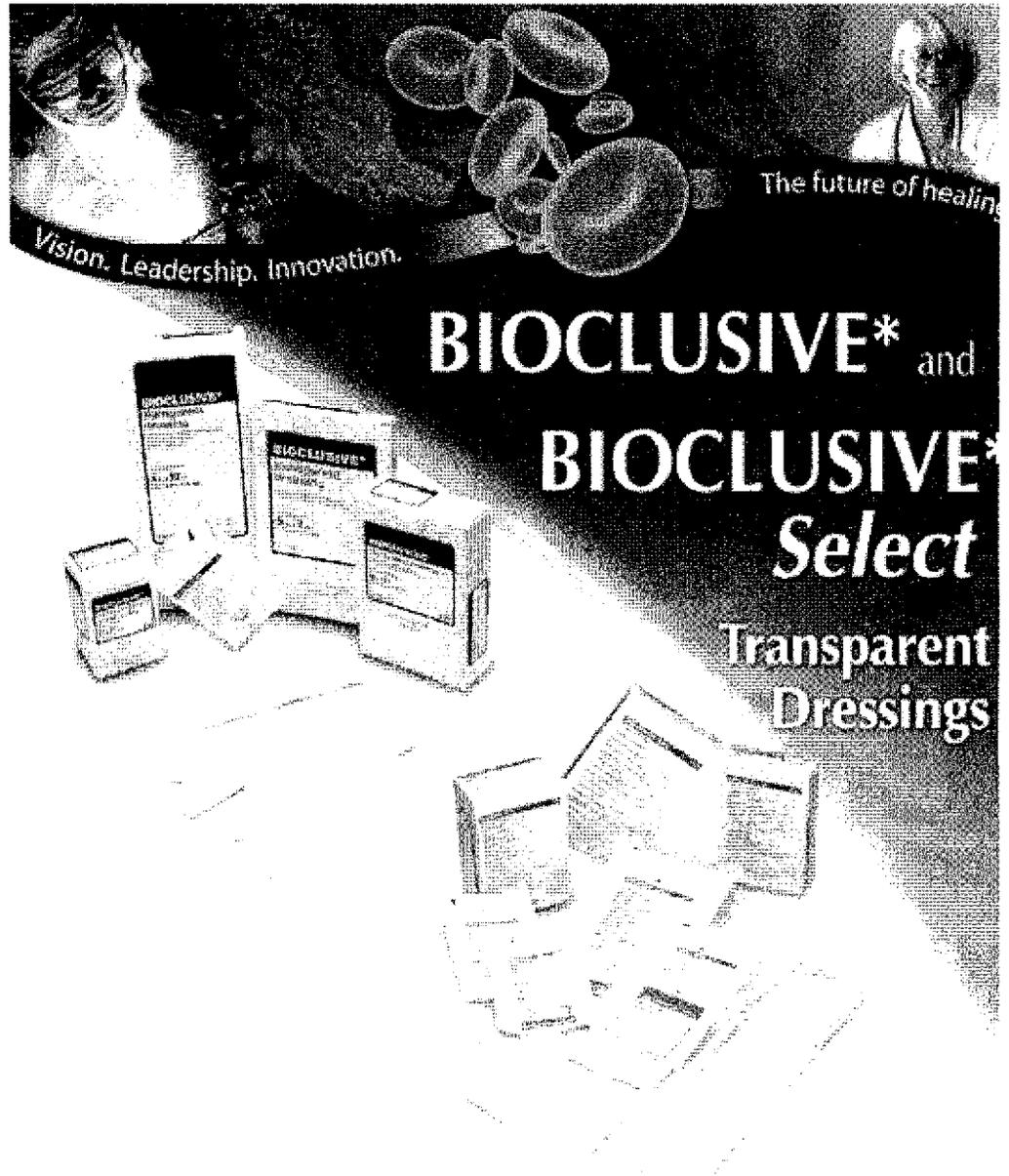
Contact Us

- [Contact Advanced Wound Care](#)

Instructions for Use

- [How to Apply BIOCLUSIVE Select Transparent Dressing and BIOCLUSIVE Transparent Dressing](#)

Johnson & Johnson
Wound Management
A division of ETHICON, INC.



BIOCLUSIVE and BIOCLUSIVE Select Transparent Dressings are made from thin,

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transparent polyurethane film that can be used on:

Pressure Ulcers, Skin Biopsies, Donor Sites, Second-Degree Burns and Surgical Incisions

- Provides a moist wound-healing environment
- Minimizes skin irritation
- Protects site from external contamination
- Helps protect fragile tissue

Access Devices: Peripheral IVs, Central Venous Catheters, CVPs and Neonatal IVs

- Helps secure catheters, reducing mechanical irritation,
- Bacterial/viral barrier

These semi-occlusive dressings provide a bacterial/viral barrier, allow oxygen vapor transfer, permit continuous observation, and feature "easy stretch" removal which help reduce skin irritation.

*Trademark
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ACTICOAT
Antimicrobial Barrier
Dressings

ALLEVYN Wound
Management Dressings

CADESORB pH
Modulating Ointment

INTRASITE Gel -
Hydrogel Wound
Dressing

IODOSORB 0.9%
Cadexomer Iodine

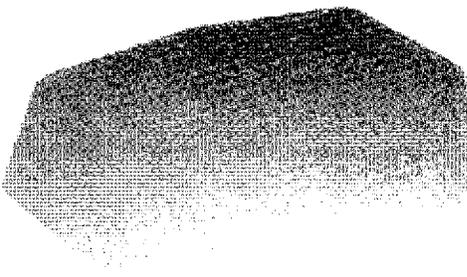
IV3000 Moisture
Responsive Catheter
Dressing

PROGUIDE Multi-layer
Compression Bandage

OPSITE Film Dressings

VERSAJET
Hydrosurgery System

IV3000 Moisture Responsive Catheter Dressing



The IV3000◊ brand offers a market leading range of moisture responsive transparent film dressings, specifically designed to meet the needs of catheter fixation and IV site protection.

IV3000◊ dressings are made from a unique REACTIC™ film, which is breathable and significantly more permeable to water vapour than ordinary film. The film is waterproof and impermeable to liquids, bacteria and viruses and reduces the risk of infection whilst offering excellent catheter stability.

IV3000◊ has pioneered the dedicated IV dressing market and today is a key brand in hospitals fight against hospital acquired infection and MRSA.

For more information, please visit www.iv3000.com

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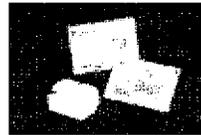
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About 3M Health Care

Profile and History

3M™ Tegaderm™ Transparent Film Dressing - Universal



[\[click to enlarge\]](#)

Transparent film dressings used to cover and secure I.V. sites to protect risk skin, or as a primary or secondary dressing over acute wounds, surgical sites, and chronic wounds. Available in a variety of sizes and shapes.

Tegaderm™ Film has a "frame" and "first aid" delivery system that make placement quick and easy. Breathable film provides a bacterial and viral barrier{1} to outside contaminants. 3M offers two, unique, different transparent adhesive dressing systems (standard and HP), giving the clinician a choice for patients with sensitive skin or a need for increased holding power in the presence of moisture.

Additional Tegaderm™ Film sizes and configurations can be found in the sections:

3M™ Tegaderm™ Transparent Film Dressing—I.V. Application
3M™ Tegaderm™ Transparent Film Dressing—Wound Application

{1} - Laboratory testing has proven Tegaderm™ and Tegaderm™ HP dressings provide a viral barrier (HIV-1 and HBV) while the dressings remain intact without leakage.

Products Resources **Benefits and Applications**

Benefits

- Versatility allows you to use one product for many applications. Breathable film allows moisture vapor and oxygen exchange.
- For I.V. sites, water vapor and oxygen are easily exchanged to permit normal functioning the skin.
- Provides a moist environment for enhanced wound healing, as viscous wound exudate is more slowly evaporated through the breathable film.
- Unique, thin film conforms to the body and flexes with the skin for greater patient comfort
- Sterile, waterproof dressing provides a bacterial and viral barrier{1} to outside contaminants and allows the patient to shower.
- The dressings are available in a variety of sizes and shapes to address both wound and I.V. applications.
- Tegaderm™ Roll has a preferred delivery system that allows it to be applied with gloved hands. Tegaderm™ Roll provides all the benefits of surgical tape, while providing a waterproof bacterial, viral {1} barrier.
- 1614 and 1616 dressings offer borders reinforced with a soft cloth fabric, designed to reduce edge lift and increase patient comfort.
- The hydrophilic nature of Tegaderm™ HP (holding power) Film adhesive makes it more adherent and useful in moist conditions.
- 1620 and 1621 first aid style dressings offer reinforced edges, built-in labels and a center line for easy placement.

{1} - Laboratory testing has proven Tegaderm™ and Tegaderm™ HP dressings provide a viral

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barrier (HIV-1 and HBV) while the dressings remain intact without leakage.

Suggested Applications

To cover and protect I.V. catheter sites and secure devices to the skin:

- Peripheral and midline venous catheters
- Central venous catheters
- Implanted infusion devices (ports)
- Dialysis catheters
- Pulmonary artery catheters
- Arterial catheters
- Epidural catheters

For use in wound care and skin protection:

- Clean, closed surgical incisions
- Abrasions, skin tears, blisters
- Skin graft donor sites
- Superficial partial thickness burns
- Stage I or II pressure ulcers
- Autolytic debridement facilitated by the moist wound healing environment
- Secondary dressing
- Protective eye coverings
- Skin protection against moisture, friction

For Tegaderm™ Roll (non-sterile):

- Secondary dressing or as a primary dressing over intact skin
- Protection of at risk skin from friction and body fluids
- Waterproof fixation of primary dressings
- Fixation of medical devices

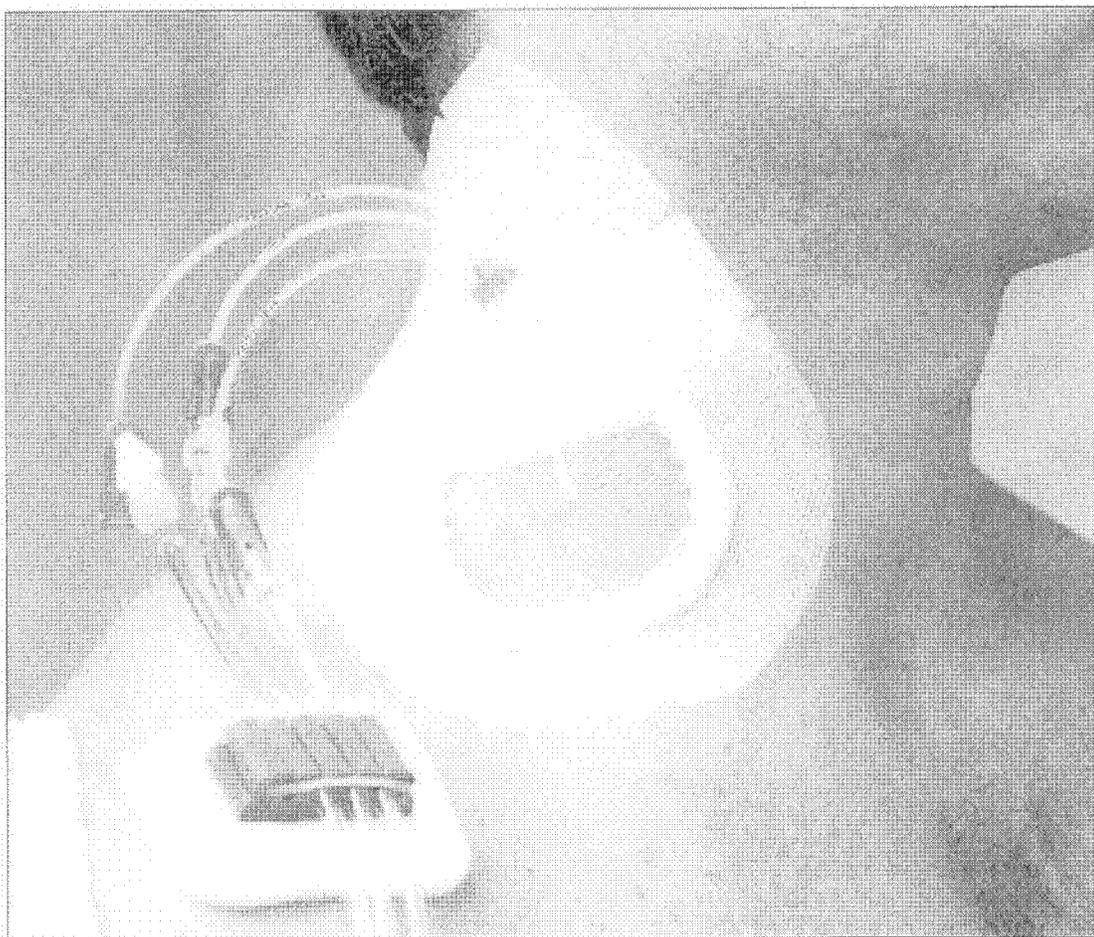
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CENTURION®

SorbaView® Ultimate Window Dressing



Technical Monograph

Viral Barrier Effectiveness

Test Method: ASTM F 1671

Testing performed by Nelson Laboratories, Inc., Salt Lake City, UT

SorbaView® Ultimate was tested for viral barrier effectiveness in accordance with ASTM F 1671, "Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System." This test method is used to measure the resistance of materials to penetration by blood-borne pathogens using a surrogate microbe under conditions of continuous liquid contact. The test method is designed to model the viral penetration of Hepatitis (B and C) and HIV transmitted in blood and other potentially infectious body fluids. Pass/fail determinations are based on the detection of viral penetration.

SorbaView® Ultimate passed the testing criteria; no viral penetration was detected.

The test results show that SorbaView® Ultimate dressings are resistant to viral penetration and behave as viral barriers. The tested Phi-X 174 bacteriophage is one of the smallest known viruses. Therefore, by inference, the test provides indirect evidence to suggest that SorbaView® Ultimate dressings would behave as a barrier to other, larger viral and bacterial contaminants.

Blood Barrier Effectiveness

Test Method: ASTM F 1670-98

Testing performed by Nelson Laboratories, Inc., Salt Lake City, UT

SorbaView® Ultimate was tested for blood barrier effectiveness in accordance with ASTM F 1670-98, "Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood." This test method is used to measure the resistance of materials to penetration by synthetic blood under conditions of continuous liquid contact. The test method helps assess the effectiveness of materials for protecting against contact with body fluids that potentially contain blood-borne pathogens. Pass/fail determinations are based on visual detection of synthetic blood penetration.

SorbaView® Ultimate passed the testing criteria; no synthetic blood penetration was detected.

The test results show that SorbaView® Ultimate dressings are resistant to blood penetration and behave as liquid barriers.

Test results on file.

Product Description

SorbaView® Ultimate is a highly permeable, self-adhesive, transparent film dressing that uses an innovative multi-layer construction.

First, an absorbent, non-adherent pad helps prevent moisture build-up by wicking away moisture from the skin to the fibrous pad, and then displacing it to the exterior non-woven fabric border. This highly absorbent pad material is fenestrated to form a “window” in the dressing.

Second, a polyurethane film membrane covers and surrounds the fenestrated pad. This thin, semi-permeable film is a strong protective barrier to external contaminants and liquids, and is visually clear, thus ideally suited for use in the care of intravenous catheter sites.

The adhesive non-woven fabric layer completes the dressing. This outer border of fabric adds strength to the dressing and conforms comfortably to patients’ skin.

SorbaView® Ultimate can be worn for long periods of time because it continuously prevents the build up of moisture from under the dressing.

Intended Use

SorbaView® Ultimate is classified as a TSM (transparent semi-permeable membrane) dressing and was designed for the treatment of peripherally inserted central catheters (PICCs), central venous catheters (CVCs), internal jugular central venous catheters (IJ CVCs), dialysis procedures and epidural catheters. It is ideally suited for a range of catheter access devices.

Design Features

- Integrated pad wicks away moisture, keeping site dry
- Easy to apply
- Stays securely in place for extended periods
- Easy to remove
- Exceptionally high Moisture Vapor Transmission Rate (MVTR)
- Non-cytotoxic adhesive is non-irritating and non-sensitizing
- Transparent window allows continuous site visibility
- Multi-layer construction is protective, breathable and comfortable to patients’ skin
- Creates an occlusive barrier against contaminants
- Conforms and responds to body contours
- Latex free
- Available in individual sterile packages, or in custom procedure trays
- U.S. Patent Nos. 7,025,749 and 6,841,715

Design Rationale

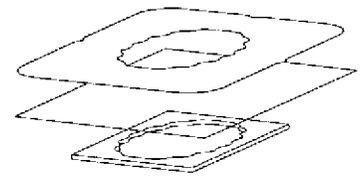
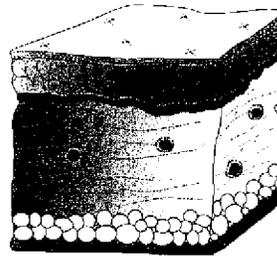
The anatomy and physiology of human skin, as the breathable protective barrier that allows the body to survive in a contaminant-filled environment, is what inspired the combination of different material layers in the design of SorbaView® Ultimate.

Skin is composed of multiple layers. The thin outer layer, or epidermis, is composed of cells which are continuously eroding while new replacement cells are multiplying to provide a protective barrier. Beneath this is the dermis, which is comprised mostly of connective fibrous tissues which create the anchoring adhesive to underlying tissues and provide for proper control of moisture and temperature.

SorbaView® Ultimate mimics skin in its innovative multi-layer construction. Its unique design utilizes a breathable outermost layer, a protective and strong lower layer which controls moisture, and a conforming adhesive layer to anchor it all securely.

Advanced Materials & Methods

The select medical-grade adhesive used in SorbaView® Ultimate has a unique combination of aggressive tack coupled with moderate peel strength, which is particularly advantageous in medical applications. This adhesive performs well in a wide range of ambient seasonal humidity and temperature environments.



The cross section of skin can be compared to the multiple layers of materials that combine to create SorbaView® Ultimate

The adhesive coating on the film is applied in a unique pattern that prevents any blockage of the film's permeability, allowing the dressing to be more breathable, highly moisture vapor permeable and to hold securely for extended time periods – even beyond seven days. The high moisture permeability of the film used in SorbaView® Ultimate creates an occlusive barrier to micro-sized contaminants and liquids, while allowing for the free exchange of gases enabling the skin to breathe normally.

Both the film and the non-woven fabric have an “omni-directional” stretch characteristic much like human skin. The needle-punched fabric moves with the skin in any direction and conforms securely to the skin surface or intravenous access device with a breathable seal. It allows the skin and the clear polyurethane film barrier to be joined with a minimum amount of adhesive and remain intact and comfortably worn to lock out contaminants. The patient benefits from this gentle, protective, net-like layer while wearing the dressing and also during its removal, which is thus made less traumatic. In addition, the added physical strength of the fabric on top of the film helps SorbaView® Ultimate to remain intact for extended periods.

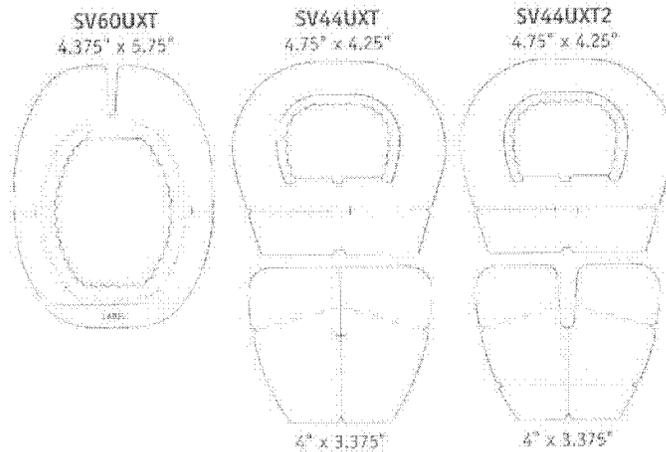
The non-adherent pad under the film is lint free and highly absorbent. This pad material is cut with “wave-like” or scalloped shape interior edges that increase the fibrous surface area. This is designed to help keep the catheter exit site dry by wicking away gaseous moisture from under the film center, into the pad, and displacing it to the exterior region of the dressing's nonwoven fabric border. The pad also adds internal strength to the dressing, making it easier to apply and remove.

The dressing is designed to have a layered quality like that of skin, and to be able to transpire moisture from the lower inside barrier film layer to the outer surface area of the fabric. The exposed fabric can and will get wet by showering and precaution should be taken to avoid saturating the dressing while bathing. The Centers for Disease Control and Prevention (CDC) guidelines recommend changing dressings should they become damp, loosened or soiled. However, with the protective film layer below the fabric, an intact dressing will always keep the site sealed. Liquids are shut out, but gases are allowed to move freely as they do in normal function of the skin. This dressing is unique in its design and holds two US Patents.

Product Profile

- Liner:** Silicone treated paper
- Pad:** Absorbent Lyocell pad – solvent-spun cellulose, 70 mil.
- Adhesive:** Polyacrylate adhesive (non-sensitizing)
- Film:** Polyurethane film, 1 mil.
- Fabric:** Dupont 8010 Sontara™ non-woven fabric, 10 mil.

Illustrated Dressing Sizes



Other dressing sizes and styles may be available; check with your representative for details.

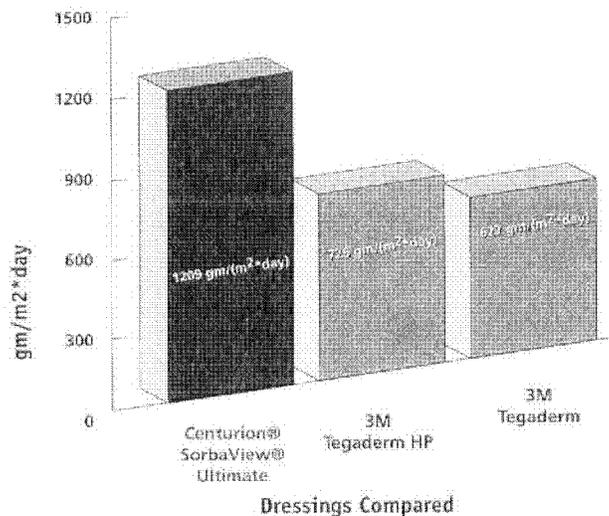
Moisture Vapor Transmission Rate

Test Method: ASTM F1249

Testing performed by MOCON Consulting and Testing Services, Minneapolis, MN

SorbaView® Ultimate was tested to measure the Moisture Vapor Transmission Rate in accordance with ASTM F1249. This is the standard test method for determining the rate of water vapor transmission through flexible barrier materials using a modulated infrared sensor. This test was performed on a Mocon 3/31 instrument.

SorbaView® Ultimate showed a Moisture Vapor Transmission Rate of 1209 gm/m²*day.



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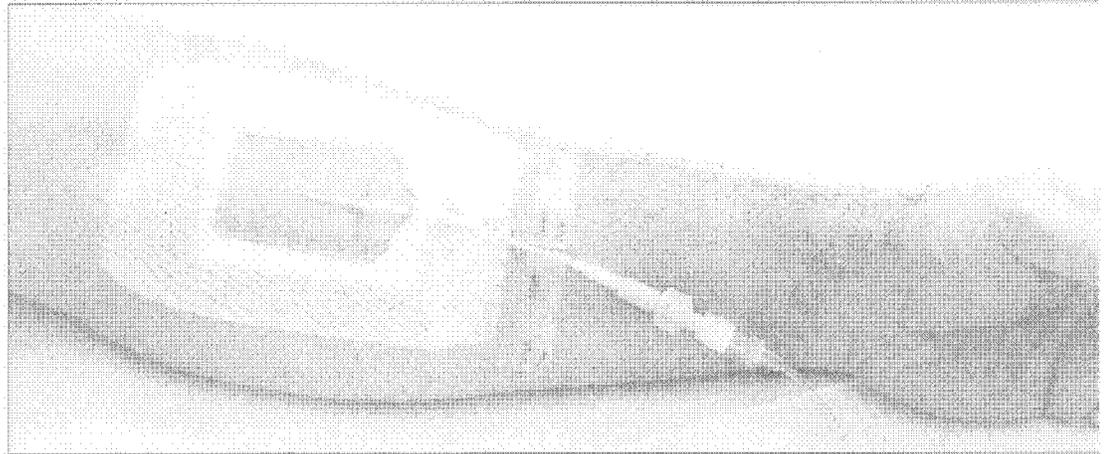
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CENTURION[®]

SorbaView[®] 2000
Window Dressing



Technical Monograph

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Viral Barrier Effectiveness

Test Method: ASTM F 1671-97b

Testing performed by Nelson Laboratories, Inc., Salt Lake City, UT

SorbaView® 2000 was tested for viral barrier effectiveness in accordance with ASTM F 1671-97b, "Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System." This test method is used to measure the resistance of materials to penetration by blood-borne pathogens using a surrogate microbe under conditions of continuous liquid contact. The test method is designed to model the viral penetration of Hepatitis (B and C) and HIV transmitted in blood and other potentially infectious body fluids. Pass/fail determinations are based on the detection of viral penetration.

SorbaView® 2000 passed the testing criteria; no viral penetration was detected.

The test results show that SorbaView® 2000 dressings are resistant to viral penetration and behave as viral barriers. The tested Phi-X 174 bacteriophage is one of the smallest known viruses. Therefore, by inference, the test provides indirect evidence to suggest that SorbaView® 2000 dressings would behave as a barrier to other, larger viral and bacterial contaminants.

Peel Adhesion (Adherence)

Test Method: (PSTC-1) 180° Peel Adhesion

Averages as tested on stainless steel after 20-30 mins.

Testing performed by DermaMed Coatings Company, Tallmadge, OH

SorbaView® 2000 was tested in accordance with PSTC-1. This test method is used to measure the adherence of the dressing (when peeled at 180° angle, to a standard steel panel).

SorbaView® 2000 showed an average peel rate of 871.3 gm.

Test results on file.

Product Description

SorbaView® 2000 is a highly permeable, self-adhesive, transparent film dressing that uses an innovative multi-layer construction.

First, an absorbent, non-adherent pad helps keep the catheter exit site dry by wicking away moisture from the skin to the fibrous pad, and then displacing it to the exterior non-woven fabric border. This highly absorbent pad material is fenestrated to form a “window” in the dressing, plus it serves as a protective blanket under bulky catheters to make patients feel more comfortable.

Second, a polyurethane film membrane covers and surrounds the fenestrated pad. This thin, semi-permeable film is a strong protective barrier to external contaminants and liquids, and is visually clear, thus ideally suited for use in the care of intravenous catheter sites.

The adhesive, fenestrated, non-woven fabric layer completes the materials in this unique multi-layer dressing. This conformable outer border of fabric is ideal for protecting catheter exit site wounds and securing access devices to patients’ skin.

Intended Use

SorbaView® 2000 is classified as a TSM (transparent semi-permeable membrane) dressing and can be used in the treatment of central venous catheter (CVC), peripherally inserted central catheter (PICC), and peripheral intravenous site management; dialysis procedures; implanted port access; epidural catheter securement; and to cover and protect superficial wounds, skin tears, and abrasions. SorbaView® 2000 can be worn for long periods of time because it continuously prevents the build up of moisture from under the dressing.

Design Features

- Integrated pad wicks away moisture, keeping site dry
- Easy to apply
- Stays securely in place with easy peel removal
- Designed to be used in seven day dressing change protocols
- High Moisture Vapor Transmission Rate (MVTR)
- Non-cytotoxic adhesive is non-irritating and non-sensitizing
- Transparent window allows continuous site visibility
- Multi-layer construction is protective, breathable and comfortable to patients’ skin
- Creates an occlusive barrier against contaminants
- Various sizes accommodate a wide range of access devices
- Conforms and responds to body contours
- Latex free
- Available in individual sterile packages, or in custom procedure trays
- U.S. Patent No. 6,841,715

Design Rationale

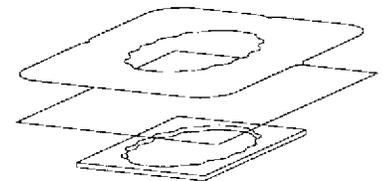
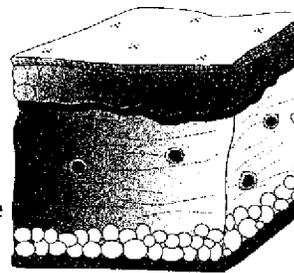
The anatomy and physiology of human skin, as the breathable protective barrier that allows the body to survive in a contaminant-filled environment, is what inspired the combination of different material layers in the design of SorbaView® 2000.

Skin is composed of multiple layers. The thin outer layer, or epidermis, is composed of cells which are continuously eroding while new replacement cells are multiplying to provide a protective barrier. Beneath this is the dermis, which is comprised mostly of connective fibrous tissues which create the anchoring adhesive to underlying tissues and provide for proper control of moisture and temperature.

SorbaView® 2000 mimics skin in its innovative multi-layer construction. Its unique design utilizes a breathable outermost layer, a protective and strong lower layer which controls moisture, and a conforming adhesive layer to anchor it all securely.

Advanced Materials & Methods

The select medical-grade adhesive used in SorbaView® 2000 has a unique combination of aggressive tack coupled with moderate peel strength, which is particularly advantageous in medical applications. This adhesive performs well in a wide range of ambient seasonal humidity and temperature environments.



The cross section of skin can be compared to the multiple layers of materials that combine to create SorbaView® 2000

The adhesive coating on the film is applied in a unique pattern that prevents any blockage of the film's permeability, allowing the dressing to be more breathable, highly moisture vapor permeable and to hold securely for extended time periods – even beyond seven days. The high moisture permeability of the film used in SorbaView® 2000 creates an occlusive barrier to micro-sized contaminants and liquids, while allowing for the free exchange of gases enabling the skin to breathe normally.

Both the film and the non-woven fabric have an “omni-directional” stretch characteristic much like human skin. The needle-punched fabric moves with the skin in any direction and conforms securely to the skin surface or intravenous access device with a breathable seal. It allows the skin and the clear polyurethane film barrier to be joined with a minimum amount of adhesive and remain intact and comfortably worn to lock out contaminants. The patient benefits from this gentle, protective, net-like layer while wearing the dressing and also during its removal, which is thus made less traumatic. In addition, the added physical strength of the fabric on top of the film helps SorbaView® 2000 to remain intact for extended periods.

The non-adherent pad under the film is lint free and highly absorbent. This pad material is cut with “wave-like” or scalloped shape interior edges that increase the fibrous surface area. This is designed to help keep the catheter exit site dry by wicking away gaseous moisture from under the film center, into the pad, and displacing it to the exterior region of the dressing's nonwoven fabric border. The pad also adds internal strength to the dressing, making it easier to apply and remove.

The dressing is designed to have a layered quality like that of skin, and be able to “transpire” moisture from the lower inside barrier film layer to the outer surface area of the fabric. The exposed fabric can and will get wet by showering and precaution should be taken to avoid saturating the dressing while bathing. The Centers for Disease Control and Prevention (CDC) guidelines recommend changing dressings should they become damp, loosened or soiled. However, with the protective film layer below the fabric, the site will always be sealed. Liquids are shut out, but gases are allowed to move freely as they do in normal function of the skin. This dressing's unique design is patented.

Product Profile

Liner: Silicone treated paper

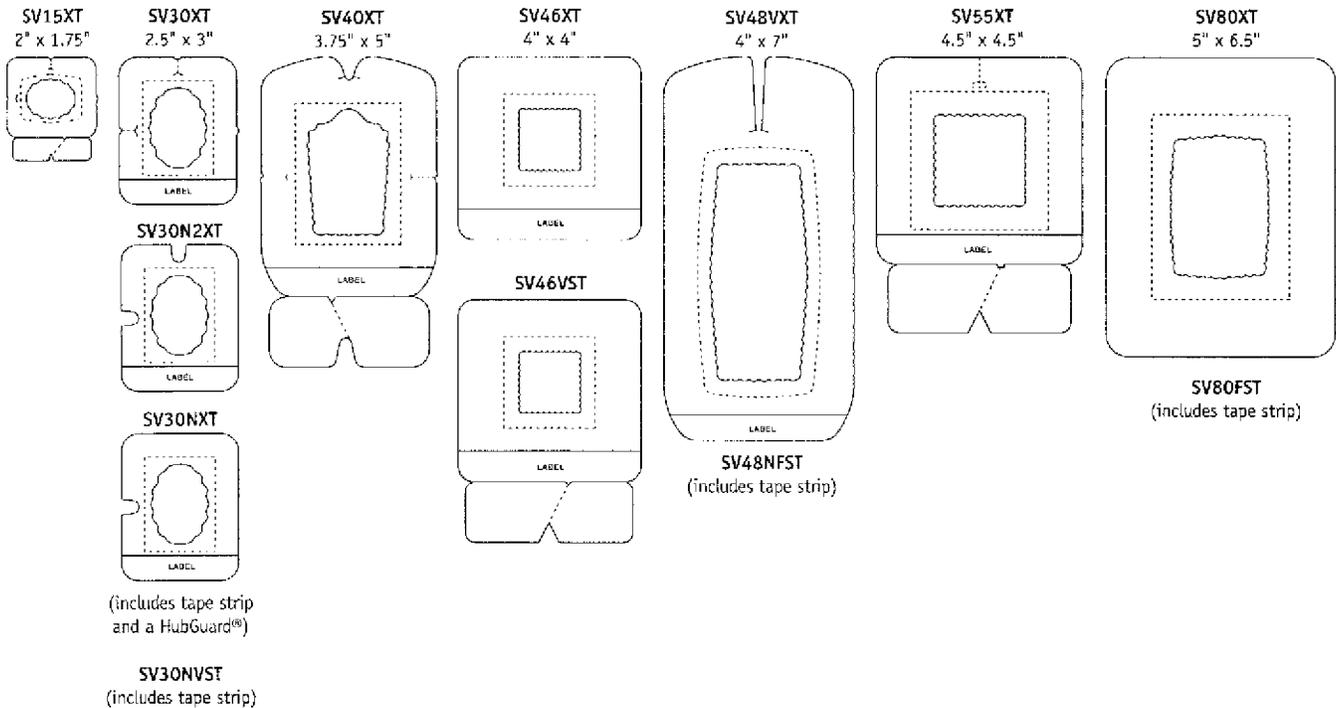
Pad: Absorbent Lyocell pad – solvent-spun cellulose, 70 mil.

Adhesive: Polyacrylate adhesive (non-sensitizing)

Film: Polyurethane film, 1 mil.

Fabric: Dupont 8010 Sontara™ non-woven fabric, 10 mil.

Illustrated Dressing Sizes



Other dressing sizes and styles may be available; check with your representative for details.

Blood Barrier Effectiveness

Test Method: ASTM F 1670-98

Testing performed by Nelson Laboratories, Inc., Salt Lake City, UT

SorbaView® 2000 was tested for blood barrier effectiveness in accordance with ASTM F 1670-98, "Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood." This test method is used to measure the resistance of materials to penetration by synthetic blood under conditions of continuous liquid contact. The test method helps assess the effectiveness of materials for protecting against contact with body fluids that potentially contain blood-borne pathogens. Pass/fail determinations are based on visual detection of synthetic blood penetration.

SorbaView® 2000 passed the testing criteria; no synthetic blood penetration was detected.

The test results show that SorbaView® 2000 dressings are resistant to blood penetration and behave as liquid barriers.

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Attachment 6
Updated Summary Statement

Premarket Notification (510(k)) Summary

1. Sponsor Information:

3M Health Care
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144-1000

Contact Person: Maria Ruiz
Senior Regulatory Affairs Associate
Phone Number: (651) 736-2733
FAX Number: (651) 737-5320

Date of Summary: April 18, 2008

2. Device Name and Classification:

Common or Usual Name: Antimicrobial I.V. Securement Dressing

Proprietary Name: 3M™ Tegaderm™ CHG Dressing
(Chlorhexidine Gluconate I.V. Securement Dressing)

Classification Name: Antimicrobial Dressing, Unclassified

Performance Standards: None

3. Predicate Devices:

- 3M™ Tegaderm™ CHG Dressings (K063458, cleared April 5, 2007)
- Bioclusive Transparent Film Dressing (K895207, cleared September 28, 1989)
- Opsite IV 3000 (K895353, cleared December 14, 1989)
- Tegaderm™ Transparent Film Dressings (K973036, cleared November 12, 1997)
- SorbaView® Ultimate Window Dressing
- SorbaView® 2000

4. Description of Device:

3M™ Tegaderm™ CHG Dressing, Chlorhexidine Gluconate I.V. Securement Dressing, is used to cover and protect catheter sites and to secure devices to skin. Available in a variety of shapes and sizes to meet the needs of the caregiver.

Tegaderm™ CHG Dressing consists of a transparent adhesive dressing and an integrated pad containing Chlorhexidine Gluconate (CHG), a well-known antiseptic agent with broad-spectrum antimicrobial and antifungal activity. The dressing is a barrier to liquid (waterproof), bacteria and viruses* and yeast, and

protects the IV site from outside contamination. The pad absorbs up to eight times its weight in fluid. *In vitro* testing (log reduction, barrier, and zone of inhibition) demonstrates that the Tegaderm™ CHG dressing has an antimicrobial effect against, and is a barrier to, the passage of a variety of gram-positive and gram-negative bacteria and yeast in the dressing. Tegaderm™ CHG Dressing is transparent, allowing continual site observation, and is breathable, allowing good moisture vapor exchange.

**In vitro* testing has proven that Tegaderm CHG provides a viral barrier from viruses 27 nm in diameter, (e.g. HCV) or larger (e.g. HBV and HIV) while the dressing remains intact without leakage.