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K031684  
page  
1/3

### 510(k) Summary of Safety and Effectiveness

(according to document 807.92: Content and format of a 510 (k))

(1)

**Submitter's name:** Biomet Merck GmbH

**Submitter's address:** Altes Widalmi 12, 3216 Ried bei Kerzers, Switzerland

**Contact person:** Dr. Thomas Kiewitt/ Dr. Adelheid Liebendörfer

**Date:** 28 th of May 2003

(2) **Name of the device:** Topkin®, wound dressing

(3) **Legally market device to which the submitter claims equivalence:**

Bioderm® thin film wound dressing, FDA no.: K982939

(4) **Description of Topkin®:**

**Topkin® foil** is a synthetic, polymeric, transparent foil for temporary coverage of non-infected skin defects, such as superficial wounds, under sterile conditions.

**Topkin® adhesive** is made from the same ingredients like the Topkin® foil plus Titanium dioxide and is used for the fixation of Topkin® foil on healthy skin. The fixation is mediated by cohesive forces between the Topkin® foil, the Topkin® adhesive and the healthy skin.

**Material used:**

**Topkin® foil:**

Lactide-caprolactone copolymers

**Topkin® Adhesive:**

99 % Oligocaprolactone-co-lactide and 1 % Titanium dioxide

**Scientific concepts, significant physical and performance characteristics:**

To avoid resp. minimize regular painful wound dressing changes this concept of a degradable wound dressing which can remain on the wound (Topkin®) resp. healthy skin (Topkin® adhesive) has been developed. It consists of the degradable copolymer Topkin® foil and the Topkin® adhesive. Due to the degradability of the material the dressing needs to be changed rarely or not at all during the healing process. Under normal conditions the wound covering is degraded within approximately 4 weeks.

The Topkin® foil degrades physically. When it comes into the body it is physiologically metabolized.

Hydrolytic degradation of the polymers liberates 6—hydroxycaproic acid and D,L-Lactic acid. L-lactate is degraded in the Cori-Cycle (lactid acid cycle) to glucose.

D-Lactide is metabolized in two different ways: it can be excreted renally or breathed out as CO<sub>2</sub>.

6-Hydroxycapronacid is metabolized via  $\beta$ -oxidation to Acetyl-CoA units and then is metabolized in the Citrate-Cycle.

Poly lactides are extensively documented polymers which on account of their physical, chemical as well as biological properties have already proved effective in various medical applications.

Topkin® foil has been tested experimentally and is considered to be biocompatible. Topkin® adhesive as well underwent toxicological assessment and too is deemed to be suitable for the described application.

**(5) Statement of the intended use of the device:**

Topkin® is indicated for temporary coverage of non-infected skin defects, such as superficial wounds under sterile conditions.

Topkin® adhesive is made from the same constituents plus Titanium dioxide to make it visible. It has been developed to fix Topkin® on healthy skin.

**(6)****Summary of the technological characteristics of the new device in comparison to those of the predicate device**

The intended use of Topkin® is identical to the legally marketed device Bioderm®. Both wound dressings are transparent and are permeable to water vapor and oxygen therefore leading to a favourable healing climate in and around the wound.

The effectiveness and substantial equivalence of Topkin® was determined by comparing relevant data. The results showed that Topkin® is at least equal to Bioderm® and thus fulfilled its intended use.

K031684  
page 3/3



The non-clinical performance data comparing Topkin® with the predicate device Bioderm® confirm that in all relevant properties Topkin® is at least as good as Bioderm and that both wound dressings are substantially equivalent in their indication and effect on the wound healing process and pain relief.

In summary, Topkin® is safe and effective for use in the above mentioned indications. Topkin® is substantially equivalent to Bioderm® in terms of indication and intended use.

Ried bei Kerzers

5/28/03

Dr. Thomas Kiewitt



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 30 2003

Dr. Thomas Kiewitt  
Managing Director  
Biomet Merck GmbH  
Atles Widalmi 12  
Ried Bei Kerzers  
Switzerland 3216

Re: K031684  
Trade/Device Name: Topkin<sup>®</sup> Wound Dressing  
Regulatory Class: Unclassified  
Product Code: FRO  
Dated: September 17, 2003  
Received: September 22, 2003

Dear Dr. Kiewitt:

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.

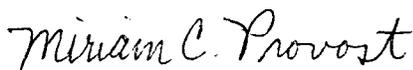
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 - Dr. Thomas Kiewitt

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

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

Enclosure

**STATEMENT OF INDICATIONS FOR USE**

510(k) Number K031684

**Device Name:** Topkin® wound dressing

**Indications for Use:**

For temporary coverage of non-infected skin defects, such as superficial wounds, under sterile conditions.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use   X    
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use \_\_\_\_\_  
(Optional Format 1-2-96)

Miriam C. Provost  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K031684