

K093729
Page 1 of 2

510(k) Summary

JUN - 8 2010

Trade Name: GuardIVa™
Common Name: Dressing, Wounds, Drug
Classification Name: Unclassified
Product Code: FRO
Predicate Device(s): BioPatch® (K003229)
BloodSTOP™ (K072681)
Seal-On™ Hemostatic Powder Spray
(K010933)

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Date of Preparation: 09 April 2010

Description of the Device:

The HemCon GuardIVa™ Antimicrobial Hemostatic IV Dressing is a sterile hydrophilic polyurethane absorptive foam impregnated with chlorhexidine gluconate (CHG) and microdispersed oxidized cellulose (m•doc™) and backed with a non-stick polyethylene film. This one inch diameter dressing is packaged in a peelable low density polyethylene (LDPE) and Tyvek® pouch. The dressing will be provided both sterile and non-sterile. The sterile pouched dressing is terminally sterilized with gamma irradiation to a sterility assurance level (SAL) of 10⁻⁶. The haemostatic properties of m•doc™ provides the dressing with the ability to control surface bleeding from percutaneous catheters and vascular access sites. Chlorhexidine gluconate acts as a preservative to inhibit the growth of microorganisms within the dressing. CHG is a well known antiseptic agent with broad spectrum antimicrobial and antifungal activity against a wide range of gram positive and gram negative organisms, including methicillin resistant *Staphylococcus aureus* ATCC33591 (MRSA), vancomycin-resistant *Enterococcus faecalis* ATCC51299 (VRE) and *Acinetobacter baumannii* ATCC15308. GuardIVa™ has not been clinically tested for its ability to reduce local infections, catheter related blood stream infections (CR-BSI) and skin colonization of microorganisms commonly related to CR-BSI.

Intended Use:

The HemCon GuardIVa™ Antimicrobial Hemostatic IV Dressing is intended for use as a hydrophilic wound dressing to absorb exudate, cover and protect catheter sites. Common applications include IV catheters, other intravenous catheters and percutaneous devices. It is also indicated for control of surface bleeding from percutaneous catheters and vascular access sites.

K093729
page 2 of 2

Basis for Substantial Equivalence:

GuardIVa™ is substantially equivalent to at least three predicate devices, all of which are in the same FDA classification as GuardIVa™.

- 1) BioPatch® a polyurethane foam dressing containing the antimicrobial agent CHG.
- 2) BloodSTOP™ a standard dressing impregnated with a hemostatic agent from plant derived cellulose.
- 3) Seal-On™ Hemostatic Powder Spray which is made of the hemostatic agent microdispersed oxidized cellulose (m•doc™)

BioPatch® has demonstrated the safety and efficacy of a polyurethane foam dressing containing the antimicrobial agent CHG. GuardIVa™ is also a polyurethane foam dressing impregnated with the same antibacterial agent CHG as the predicate device BioPatch® (K003229). GuardIVa™ is made from the same material, is available in the same size configurations, and is packaged in a Tyvek® and LDPE pouch like this predicate. An intended use for BioPatch® (K003229) is as a hydrophilic wound dressing that absorbs exudate and covers the wound caused by the use of vascular and non-vascular percutaneous medical devices.

The GuardIVa™ antimicrobial haemostatic IV dressing has m•doc™ impregnated in the polyurethane foam to help control surface bleeding. This design and intended use is substantially equivalent to the other two predicate devices: Seal-ON™ (K010933) and BloodSTOP® (K072681). BloodSTOP™(K072681) has demonstrated the safety and efficacy of a standard dressing impregnated with a haemostatic agent and Seal-On™ Hemostatic Powder Spray (K010933) has demonstrated the safety and efficacy of microdispersed oxidized cellulose (m•doc™) as a haemostatic agent. The haemostatic agent in GuardIVa™ is the same as that in the predicate device Seal-ON™ and is substantially equivalent to BloodSTOP® as both are derived from plant source cellulose.

Summary of performance testing:

The efficacy of the GuardIVa™ antimicrobial haemostatic IV dressing was demonstrated with *in vitro*, *in vivo* and *ex vivo* performance testing using the predicate device BioPatch® as a comparator. GuardIVa™ displayed superior haemostatic efficacy and a higher absorption capacity than BioPatch®. The antibacterial efficacy of GuardIVa™ was tested *in vitro* using AATCC Test Method 100-2004, a quantitative, direct contact method for the evaluation of the degree of antimicrobial activity of a test article. GuardIVa™ demonstrated greater than log 4 reductions of all the organisms tested.

Conclusion:

The conclusion drawn from the technological characteristics and non-clinical performance data is that the device is as safe and effective as the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room -WO66-G609
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JUN - 8 2010

Re: K093729
Trade/Device Name: GuardIVa™
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 25, 2010
Received: May 26, 2010

Dear Mr. Hawkins:

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

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

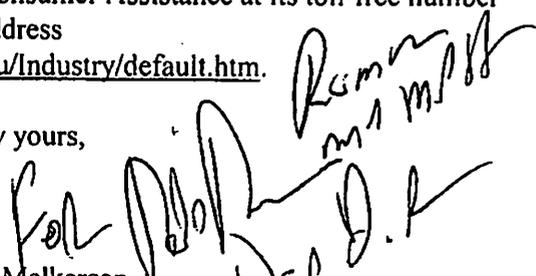
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

Page 2 - Mr. Kevin Hawkins

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

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

Sincerely yours,


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

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Enclosure

K093729
Page 1 of 1

Applicant: HemCon Medical Technologies Europe Limited
510(k) Number: K093729
Device Name: GuardIVa™

Indications for Use:

The HemCon GuardIVa Antimicrobial Hemostatic IV Dressing is intended for use as a hydrophilic wound dressing to absorb exudate, cover and protect catheter sites. Common applications include IV catheters, other intravenous catheters and percutaneous devices. It is also indicated for control of surface bleeding from percutaneous catheters and vascular access sites.

Prescription Use
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krone for MKM
(Division Sign-Off)

Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number

K093729