

Steripak

K972185

MAR - 5 1998

510(k) Summary

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

"The assigned 510 (k) number is K972185 ."

1. Submitter Information

Steripak Limited
Goddard Road, Astmoor
Runcorn, Cheshire WA7 1QF
England

Contact Person: Steve Forrester-Coles
Site Operations Director

Phone: 44-1-928-579110
FAX: 44-1-928-579540

2. Name of Device

Trade/Proprietary Name: 20 mL Normal Saline Topical Solution,
0.9% w/v Sodium Chloride
Common/Usual Name: Normal Saline Topical Solution
0.9%w/v Sodium Chloride
Classified Name: Liquid Bandage

3. Predicate Device

The predicate device identified for the substantial equivalence claim is Brennen Medical, Incorporated's Sterile Saline Solution. This product is distributed by Brennen Medical, Inc. under their 510 (k) K935060, Brennen Medical Sterile Saline Solution, cleared on January 10, 1994. This product is classified as a Liquid Bandage. Brennen Medical's Sterile Saline Solution is an 8 fluid ounce pressurised container of sterile, isotonic buffered solution containing sodium chloride, boric acid, sodium borate and purified water. The Brennen Medical product is for moistening and lubricating absorbent wound dressings prior to removal from the wound area.

Steripak

4. Description of the Subject Device

The subject device is a 20 mL Normal Saline Topical Solution, 0.9% w/v Sodium Chloride. It is used for moistening and lubricating absorbent wound dressings prior to removal from the wound area. Normal Saline Topical Solution 0.9% w/v is a unit-dose low density polyethylene vial containing a clear, colourless, aqueous solution. Normal Saline Topical Solution contains 0.9% w/v Sodium Chloride USP in Water for Injection USP. The formulation contains no additives.

5. Intended Use of the Subject Device

The Normal Saline Topical Solution 0.9% w/v is for moistening and lubricating absorbent wound dressings prior to removal from the wound area. To use, the plastic unit-dose vial is first separated from the strip of vials then opened by twisting off the top of the vial. The solution in the plastic unit-dose vial is dispensed using one of two methods. To achieve a directional stream of solution, squeeze firmly. To obtain drop by drop dispensing, invert the vial and squeeze gently. Normal Saline Topical Solution 0.9% w/v is a single use product. Any solution remaining in the plastic unit-dose vial should be discarded.

6. Technological Characteristics of the Subject Device Compared to the Predicate Device

The predicate device identified for the substantial equivalence claim is Brennen Medical, Incorporated's Sterile Saline Solution. The subject device, and the predicate device, Brennen Medical's Sterile Saline Solution are both topical sterile saline solutions classified as a "liquid bandage" intended for moistening and lubricating absorbent wound dressings prior to removal from the wound area. Comparison for the Normal Saline Topical Solution 0.9% w/v product and the Brennen Medical product supports that they are substantially equivalent. Details of the substantial equivalence claim are provided in Attachments 3 through 8. Although there are technological differences between the subject device and the predicate device, these technological differences do not raise new questions of safety and effectiveness.

Steripak

7. **Signature of Applicant**

Steripak Limited,

John William Holloway BSc. CChem MRSC MBIRA
Head of Product Development and Regulatory Affairs



Signature

29th October 1997
Date



MAY - 1 2007

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

John William Holloway BSc. Cchem MRSC MBIRA
Head of Product Development and Regulatory Affairs
Steripak Limited
Goddard Road, Astmoor
Runcorn, Cheshire WA7 1QF
England

Re: K972185
20mL Normal Saline Topical Solution, 0.9% w/v Sodium Chloride
Regulatory Class: Unclassified
Product Code: FRO
Dated: February 4, 1998
Received: February 6, 1998

Dear Mr. Holloway:

This letter corrects our substantially equivalent letter of March 5, 1998.

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 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 (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act including requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration and the following limitations:

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

4. This device may not be labeled as a treatment or a cure for any type of wound.

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

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); 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.

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

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

Sincerely yours,

for [Signature]
Mark N. Melkerson *DSP D.I.*
Director *4/24/07*
Division of General, Restorative *(ACIRN)*
and Neurological Devices *Dir of MS DRG*
Office of Device Evaluation
Center for Devices and
Radiological Health

Steripak

K972185

Indications For Use Statement

510(k) Number (if known): K972185

Device Name: 20mL Normal Saline Topical Solution

Indications For Use:

20mL Normal Saline Topical Solution is used for moistening and lubricating absorbent wound dressing prior to removal from the wound area.

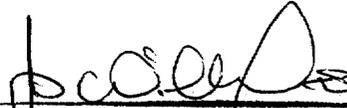
(Please Do Not Write Below This Line - Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X

Over-The-Counter Use _____

(Per 21 CFR § 801.109)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972185