

K993969

DEC 30 1999

Rev01.12.99

Section 15
\$10K Summary
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Submitter: Winchester Laboratories LL
Mr. Howard Rose
President and CEO

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Batavia, IL 60510

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Authorized Regulatory Agent
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Date Prepared: November 19, 1999

Trade Name: Saljet Single Dose Sterile Saline Topical Solution, 0.9% w/v Sodium Chloride

Common Name: Normal Saline Topical Solution, 0.9% w/v Sodium Chloride

Classification Name: Solution, Wound Dressing

Predicate Device: Steripak Limited
20 ml. Normal Saline Topical Solution
0.9% w/v Sodium Chloride

Description: 30-ml. polyethylene vial containing Saline Topical Solution, 0.9% w/v Sodium Chloride Solution. Single-use.

Indications for Use: For use in moistening and lubricating absorbent wound dressings for traumatic wounds, cuts, bruises and minor burns prior to removal from the wound area.

Substantial Equivalence: The product is similar in function and intended use to Steripak 20 mL Normal Saline Topical Solution manufactured by Steripak Limited and includes among it's labeled uses for moistening and lubricating absorbent wound dressing.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 1 2007

Mr. Howard Rose
President and Chief Executive Officer
Winchester Laboratories, LLC
325 North Water Street
Batavia, Illinois 60510

Re: K993969
Trade Name: Saljet Single Dose Sterile Saline Topical Solution
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 19, 1999
Received: November 23, 1999

Dear Mr. Rose:

This letter corrects our substantially equivalent letter of December 30, 1999.

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 (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.

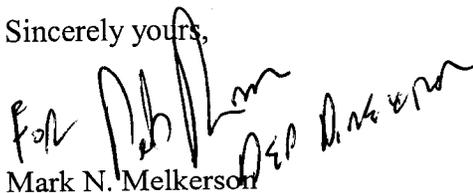
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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



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

K993969

Rev 01, 12/99

Section 3
Intended Use of Device
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Device Name: Saljet Single Dose Sterile Saline Topical Solution
0.9% w/v Sodium Chloride

Indications for Use: For use in moistening and lubricating absorbent wound dressings for
traumatic wounds, cuts, bruises and minor burns 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~~
(Per 21 CFR 801.100)

OR

Over - the - Counter Use

Russell Ferguson for 5212

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K993969