

AUG 18 1998

**SECTION E:****510(k) SUMMARY**

1. Submitted by: ACU-PAK, Inc.  
2 Perimeter Road East  
Londonderry, NH 03053  
Phone (603) 668-7688  
Fax (603) 668-1102  
  
Contact: Carol Thompson  
Regulatory Manager  
  
Preparation Date: 05/29/98
2. Device Name: Sterile Saline Solution 0.9% and Sterile Water  
  
Common Name: Sterile Saline, Sterile Water  
  
Classification Name: Catheter and Tip, Suction
3. Predicate devices: K922033 - Saline Solution 0.9%  
K933526 - Sterile Water  
Trinity Laboratories  
Salisbury, MD 21801  
  
KA05950 - Sterile Saline Solution  
KF11560 - Sterile Water  
Superior Plastics Products  
Cumberland, RI 02864  
(company purchased by)  
Kendall Healthcare Products Company  
Mansfield, MA 02048  
  
K9544<sup>442</sup> - 0.9% Isotonic Saline, Sterile  
Sterile Water  
MedCare Medical Group  
East Swanzey, NH 03446

4. Device Description:

ACU-PAK Sterile Saline Solution 0.9% and Sterile Water are used for the irrigation of medical devices. The device consists of 100ml of Saline Solution at a concentration of 0.9% or Water contained within a 100cc polyethylene wide mouthed bottle. The closure is a 38/400 white polypropylene cap fitted with an F 217 liner. A printed tamper-evident band is placed over the top of the bottle. Each bottle contains a product label displaying a lot code and expiration date.

5. Intended use of the device:

ACU-PAK Sterile Saline Solution 0.9% and Sterile Water are used for the irrigation of medical devices. These products are **not for injection**.

6. Technological characteristics:

ACU-PAK Sterile Saline Solution 0.9% and Sterile Water are identical to the predicate devices. All of the predicate devices contain 100 ml of 0.9% Saline or Water packaged in a 100ml polypropylene bottle. The closures are 38/400 caps with F-217 liners. All of the predicate devices have a tamper-evident shrink band.

7. Additional Equivalency information:

**ACU-PAK, Inc. is the contract manufacturer** for all of the predicate devices. Manufacture of these products has been ongoing for the past 9 years. ACU-PAK Sterile Saline Solution 0.9% and Sterile Water is identical to predicate devices.



Carol Thompson  
Regulatory manager



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 18 1998

Ms. Carol Thompson  
Regulatory Manager  
ACU-PAK, Incorporated  
2 Perimeter Road East  
Londonderry, New Hampshire 03053

Re: K981905  
Trade Name: Sterile Saline Solution 0.9% Catalog No.  
10290, Sterile Water - Catalog No. 10291  
Regulatory Class: II  
Product Code: FOZ  
Dated: May 29, 1998  
Received: June 1, 1998

Dear Ms. Thompson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

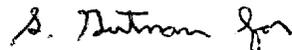
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control,  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Ver/ 3 - 4/24/96

Applicant: ACU-PAK, Inc.

510(k) Number (if known): K 981905

Device Name: Sterile Saline Solution 0.9% / Sterile Water

Indications For Use:

ACU-PAK Sterile Saline Solution 0.9% / Sterile Water are used in health care facilities for the irrigation of general medical devices. It is used as a lubricant for suction catheters.

*Arne Nauvan for P&C*  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K981905

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  OR Over-The-Counter

(Per 21 CFR 801.109)

(Optional Format 1-2-96)