

Alexander Manufacturing

A. Summary

Alexander Manufacturing Company battery Part Number MC146X is a battery comprised of 6 mercuric oxide cell(s). Testing data is located in Appendix C. Alexander Part Number MC146X is substantially equivalent to Sabretek 6060 Homerun Volumetric Infusion Pump (K941984) and other 8.4 volt (9-volt) applications battery.

Cells are assembled into batteries at Alexander Manufacturing Company's facility in Mason City, Iowa. They are assembled under the auspices of 21 CFR Part 820 Good Manufacturing Practice for Medical Devices (GMP) and ISO 9001.

Alexander Manufacturing Company is ISO 9001 registered by the National Standards Authority of Ireland (NSAI). Appendix A contains a copy of our registration.

B. Submitter

Alexander Manufacturing Company
1511 South Garfield Place
Mason City, Iowa 50401

C. Contact Person - Ken Heimendinger

D. Date of Application - 5/14/98

E. Trade Name - MC146X

F. Common Name - Primary Battery

G. Substantially Equivalent to - (K941984) Sabretek 6060 Homerun Volumetric Infusion Pump (K941984) and other 8.4 volt (9-volt) applications battery.

H. Description - MC146X is a 8.4 volt/800 mAh battery pack which replaces Sabretek 6060 Homerun Volumetric Infusion Pump (K941984) and other 8.4 volt (9-volt) applications battery (K941984).

I. Indications for Use - Each battery pack is a replacement for the OEM battery pack. Each is used in the same indications as that of the original batteries supplied with the original equipment. The MC146X meets all US Government ANSI/NEDA specs, so is therefore a replacement for the common "9-volt" battery.

J. Indications for Use form(s) utilizing the format provided by the Center for Devices and Radiological Health are found in Section III, Page 3.

K. Alexander Manufacturing Company is submitting a 510(k) Statement in lieu of a Summary of Safety and Effectiveness. This 510(k) Statement can be found in Appendix B.

L. Truthful and Accurate Statement - A Truthful and Accurate Statement as required by 21 CFR 807.87(j) is located in Appendix D.



AUG 3 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Ken Heimendinger
Alexander Manufacturing Company
1511 South Garfield Place
Mason City, Iowa 50401

Re: K981776
Trade Name: Alexander Manufacturing Co. Battery Part
Number MC146X
Regulatory Class: II
Product Code: FRN
Dated: May 14, 1998
Received: May 20, 1998

Dear Mr. Heimendinger:

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 through 542 of

Page 2 - Mr. Heimendinger

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" (21 CFR 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/dsmamain.html>".

Sincerely yours,

S. Dutman for

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

Enclosure

K981776

510(k) Number: K981776

Device Name: MC146X

Indications for Use:

Replacement battery for Sabretek 6060 Homerun Volumetric Infusion Pump (K941984) (and other non-rechargeable 8.4 volt (9-volt) applications).

This battery is shipped only to customers who request a replacement battery for a particular device or to replace a competitor's replacement battery. The biomedical equipment technician therefore knows the intended use is as a replacement battery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cucenite

(Division Sign-Off) _____

Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K981776

Prescription Use

OR

OVER-THE-COUNTER USE _____
(optional Form 1-2-96)