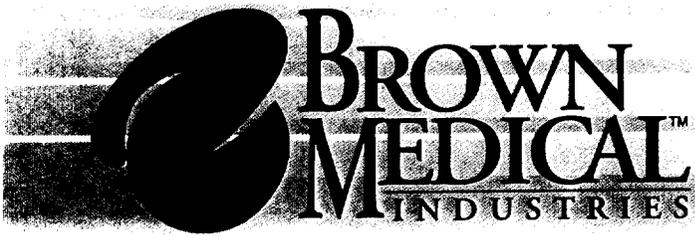


K973299



"Innovative Simplicity for a Quality Life"

Attachment I

NOV 26 1997

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.

- 1. Submitted by: Brown Medical Industries
Lakes Business Park
1300 Lundberg Drive West
Spirit Lake, IA 51360-7246

- Contact: Bob Petrosenko
Director, New Product Development

- Phone: (712) 336-4395

- Date Prepared: August 27, 1997

- 2. Name of Device: Pin Care Kit
Common/Usual Name: Unknown
Classification: Unclassified

3. Identification of predicate or legally marketed device or devices to which substantial equivalence claimed: Smith + Nephew Richards Ilizarov System, AME PinCare Management System.

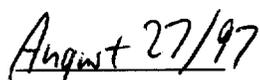
4. Description of Device: The Pin Care Kit is a comprehensive system designed to allow patients with external orthopedic fixation devices to manage their own pin site wounds at home.

5. Intended Use of the Device: The Pin Care Kit is intended for cleaning and protection of pin site wounds for patients with external fixation devices (halos, Ilizarov®, etc.). The Pin Care Kit is intended to enable patients to manage their own pin site wounds at home.

6. The Pin Care Kit has the same design, materials, function and intended use as the aforementioned devices.



Bob Petrosenko



Date



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Bob Petrosenko, MS BME
Director, New Products Development
Brown Medical Industries
Lakes Business Park
1300 Lundberg Drive West
Spirit Lake, Iowa 51360-7246

NOV 26 1997

Re: K973299
Trade Name: Pin Care Kit
Regulatory Class: Unclassified
Product Code: EFQ
Dated: August 27, 1997
Received: September 2, 1997

Dear Mr. Petrosenko:

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 (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. 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 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, FDA will verify such assumptions. Failure to

comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

In addition, we have determined that your device kit contains Sterile Water for Irrigation which is subject to regulation as a drug. Our substantially equivalent determination does not apply to the drug component of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug component. For information on applicable Agency requirements for marketing this drug, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0063

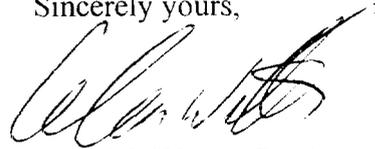
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594- 4595. 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

Page 3 - Mr. Bob Petrosenko, MS BME

number (800) 638-2041 or (301) 443-6597, or at its internet address
"<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K973299

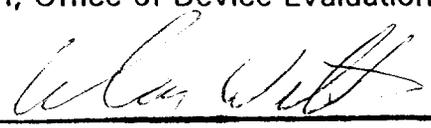
Device Name: Pin Care Kit

Indications For Use:

The Pin Care Kit is designed for use by patients wearing external orthopedic fixation devices to help them manage their own pin site wounds.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of **General Restorative Devices**
510(k) Number K973299

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)