

## 510 (k) SUMMARY

Submitter: Joerns Healthcare, Inc.  
5001 Joerns Drive  
Stevens Point, WI 54481-5040  
Ph: (715) 341-3600  
Dean Sommerfeld  
November 20, 1996 / Revised February 24, 1997

K964926

NOV - 3 1997

Device Name: Parker Bath System

Generic Name: Bathing Systems

Classification Name: Bath, hydro-massage (89ILJ)  
Class II per 21 C.F.R. § 890.5100 (immersion hydrobath)

Predicate Devices: Arjo-Century Arm and Leg Tank K923637  
Ferno Ille Hi-Lo Jr. Mobile Whirlpool K914125  
Arjo-Century Spa Shell K904106  
Parker Bath System K883308

### Description:

The Parker Bath System consists of a fiberglass base unit and a movable fiberglass tub unit. The base unit contains the air spa blower unit and the battery pack, charger, and electro-hydraulic unit for moving the tub on models with electro-hydraulic powered movement. The tub unit contains the thermostatically controlled water mixing valve, shower hose, soap dispenser and air jet system.

Some of the Parker Bath System models allow the tub to be moved vertically for ease of entry/exit of the patient and for ease of access for the caregiver. The vertical movement is powered either by a manual hydraulic pump or a 24 VDC battery powered electro-hydraulic pump unit. The tub units can all be tilted from an upright position for entry/exit/podiatry therapy to a fully reclined position for full body bathing/therapy. The tilting is powered either by a manual hydraulic pump or a 24 VDC battery powered electro-hydraulic pump unit.

The patient enters the tub through a pivoting side door and sits on a molded in seat while the tub is in the upright position. The footwell of the tub can be prefilled with warm water through the thermostatically controlled mixing valve prior to the patient entering the tub. After the door is closed and latched, the air spa blower can be turned on for podiatry and lower leg hydromassage therapy, or the tub can be reclined, allowing the water to flow up and around the patient at which point bathing can be done using the integral shower hose or the air spa blower can be turned on for a full body hydromassage. After the bath the tub is tilted to the upright position, the water flows back to the footwell and the patient can be dried off and clothed while the water flows out the drain in the footwell.

After the patient exits the tub, the tub can be disinfected by flushing the blower jets with disinfecting solution through a disinfecting port at the highest point of the blower piping. The inside of the tub can then be rinsed down with disinfecting solution and after the appropriate length of time the pipes and tub can be flushed and rinsed with clear water.

The Parker Bath System provides a safe method for the bathing and hydro-bath therapy of the patient. The hydrobath therapy is used to relieve pain and itching and as an aid in the healing process of inflamed and traumatized tissue, and it serves as a setting for the removal of contaminated tissue.

The Parker Bath System should only be used as described in the operations manual and is intended to be used in concert with well established nursing care principles.

The Parker Bath System has been designed to be safely used in the hospital, nursing home, or the home setting. The thermostat has been pre-set during manufacturing for a maximum allowable water temperature of approximately 107.5° F. Detailed installation instructions included in the operations manual instruct the health care provider in the proper set-up and use of the equipment. In addition, labeling has been provided on the bath unit specifying proper use.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV - 3 1997

Dean Sommerfeld, P.E.  
Product Engineer  
Sunrise Medical Continuing Care Group, Inc.  
5001 Joerns Drive  
Stevens Point, Wisconsin 54481-5040

Re: K964926  
Parker Bath System  
Regulatory Class: II  
Product Code: ILJ  
Dated: August 1, 1997  
Received: August 5, 1997

Dear Mr. Sommerfeld:

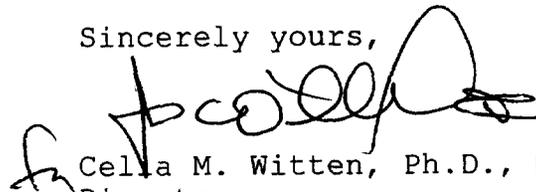
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (Pre-market 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 requirement, 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 pre-market 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.

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) 594-4659. 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,



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

Enclosure

## Indications for Use

510(k) Number (if known): K964926  
Device Name: Immersion Hydrobath

Indications for Use: To relieve pain and itching and as an aid in the healing of inflamed and traumatized tissue and as a setting for removal of contaminated tissue.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_

OR

Over-The-Counter Use X  
(Per 21 CFR 801.109)

  
\_\_\_\_\_  
(Division Sign-Off)

Division of General Restorative Devices  
510(k) Number \_\_\_\_\_

K964926