FEB 2 6 1998

K971592

510(k) SUMMARY FOR SILCRAFT CORPORATION'S SILCRAFT XTANK² MOBILE EXTREMITY WHIRLPOOL SYSTEM

Submitter's Name, Address, Telephone Number, And Contact Person

Silcraft Corporation
528 Hughes Drive
Traverse City, MI 49686

Contact: Lee Dunsirn
Silcraft Corporation
Phone: (616) 946-4221
Facsimile: (616) 946-1740

Date Prepared

May 1, 1997

Proprietary Name of the Devices

Silcraft XTank² Mobile Extremity Whirlpool System

Common or Usual Names

Extremity Whirlpool System

Classification Names

Immersion Hydrobath (21 C.F.R. § 890.5100)

Predicate Device

Ferno's Ferno IIIe Hi-Lo Jr. Whirlpool System

Intended Use

The Silcraft XTank² Mobile Extremity Whirlpool System ("the Silcraft XTank²") and Ferno's Ferno IIIe Hi-Lo Jr. Whirlpool System ("Ferno IIIe") are intended to be used for hydromassage of the user's extremities.

Principles of Operation

The principles of operation of the Silcraft XTank² and the Ferno IIIe are very similar. First, the user or the attendant (hereinafter "attendant" will refer to both the user and the attendant) moves the device to the water source. Second, the attendant fills the tank with water from a separate water source. Third, the attendant moves the device to the user or the user comes to the device. Fourth, the attendant adjust the height of the device so that is at a comfortable height for the user to soak his or her extremity while he or she is sitting next to the tank. Fifth, the user places the part of his or her body to be treated, *i.e.,* his or arm, elbow, wrist, ankles or feet in the tank. Sixth, the attendant turns the aeration on/off valve to the "on" position. Seventh, the attendant turns the aeration control valve to the desired setting, if aeration is desired. Eighth, the user soaks the affected extremity in the tank. Ninth, the attendant turns the aeration on/off valve to the "off" position when the treatment is completed. Thus, both devices have the same nine step treatment procedures.

Once treatment is completed, the attendant adds disinfectant to the tank. Next, the attendant turns the Silcraft XTank²'s aeration valve or the Ferno IIIe's power drain to the "on" position to circulate the disinfectant and water through the device's internal system and the interior of the tank following the cleaning and disinfection instructions in the device's operator's manual. The attendant then turns off the aeration or power drain. Finally, the attendant drains the tank using the device's power drain and/or manual drain. Thus, the Silcraft XTank²'s and the Ferno IIIe's cleaning and disinfection procedures also are very similar.

Technical Characteristics

The Silcraft XTank² and the Ferno IIIe have very similar technological characteristics. Each of these device primarily consists of the following components: (1) a tank to be filled with water; (2) a fill hose; (3) a base with four castors or wheels; (4) a handle to lift the device; (5) a control console; (6) a whirlpool motor; (7) whirlpool jets; (8) a power drain pump; (9) a manual drain and handle; and (10) a power supply cord.

Summary Basis for the Finding of Substantial Equivalence

The safety and effectiveness of the Silcraft XTank² is based on the long history of use of hydrobaths with very similar technological characteristics. The Silcraft XTank² and the 510(k) cleared Ferno IIIe have the same intended use and very similar principles of operation and technological characteristics. Moreover, the minor technological differences between the Silcraft XTank² and the Ferno IIIe, namely the Silcraft XTank²'s use castors instead of wheels, the additional ¼ horsepower of the device's whirlpool motor, its four additional whirlpool jets, and its electrical requirement of 5 more volts, do not raise any new questions of safety or

effectiveness. Thus, the Silcraft XTank^2 is substantially equivalent to the Ferno IIIe.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 6 1998

Mr. Howard M. Holstein
Hogan & Hartson
Representing Silcraft Corporation
555 Thirteenth Street, NW
Washington, DC 20004-1109

Re: K971592
XTank^2 Mobile Extremity Whirlpool System
K971593
Silcraft Whirlpool System
Regulatory Class: II
Product Code: ILJ
Dated: February 11, 1998
Received: February 12, 1998

Dear Mr. Holstein:

We have reviewed your Section 510(k) notifications of intent to market the devices referenced above and we have determined these devices are substantially equivalent (for the indications for use stated in the enclosures) 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 devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices 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 devices 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.

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

If you desire specific advice for your devices 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 devices, 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,

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

Enclosures

510(k) Number (if known):_____

Device Name: XTank^2 Mobile Extremity Whirlpool System

Indications For Use:

Hydromassage treatment of the user's extremities

(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 K971592

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

(Optional Format 1-2-96)