

FEB 26 1998

K971593

**510(k) SUMMARY FOR SILCRAFT CORPORATION'S SILCRAFT
WHIRLPOOL SYSTEM**

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

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Date Prepared

May 1, 1997

Proprietary Name of the Devices

(1) Silcraft Access 3700 Whirlpool System, Access 3600 Whirlpool System, Model 2001 Bather, Model 2300 Junior Sit Tub, Model 3300 Sit Tub, Model 4300 Supine Tub, Model 5300 Supine Maxi Tub, Model 4400SS Whirlpool System, and Model 5400SS Whirlpool System

(2) Silcraft Model 1800 Lift, Model 1850 Lift, Model 1400 Sling Lift; Venture Sling Lift, Venture II Sling Lift, Model 1300 Traverse Battery Operated Lift/Transfer System, and Model 1200 Traverse Battery Operated Lift/Transfer System

(3) Silcraft Disinfectant

Common or Usual Names

Whirlpool System
Patient Lift and Transfer Device
General Purpose Disinfectant

Classification Names

Immersion Hydrobath (21 C.F.R. § 890.5100)
Non-AC-powered Patient Lift (21 C.F.R. § 880.5510)
Medical Device Disinfectant (No classification regulation)

Predicate Devices

- (1) Grand Traverse Technologies, Inc.'s Freedom Bath;
- (2) Dutton-Lainson Company's Sanitas Whirlpool Bathing System;
- (3) Arjo-Century, Inc.'s Whirlpool Bathing System;
- (4) Arjo-Century, Inc.'s Height Adjustment Tank with Hygiene Chair; and
- (5) Setma, Inc.'s Setma VHT Bathing System

Intended Use

All eleven models of the Silcraft Whirlpool System are intended to be used for hydromassage and bathing.

Principles of Operation

The principles of operation of the all models of the Silcraft Whirlpool System and the predicate are very similar. First, patients access these tubs by means of certain patient transport and lift devices; in certain models, ambulatory patients enter these devices through a door in the side of the tub. Second, once the patient is comfortably position in a seated or reclining in the Silcraft tub or a predicate device's tub, the attendant (or the patient in certain models of the Silcraft Whirlpool System and a couple of the predicate devices) adjusts the valves on the control console to set the volume and temperature of the water flowing into the tub or shower. Third, the attendant (or the patient in certain models of the Silcraft Whirlpool System and a couple of the predicate devices) operates the whirlpool feature of the device by adjusting one or more aeration switches or knobs on the control panel. The attendant (or the patient in certain models of the Silcraft Whirlpool System and a couple of the predicate devices) then manually adjust both the direction of the whirlpool jets by turning them. Fourth, patients exit the Silcraft Whirlpool System's or the predicate devices' tubs by means of the same patient transport and lift devices they used to enter the tubs or by simply exiting the tub through the tub door in certain models. Fifth, the attendant cleans and disinfects the tub using the devices' built-in disinfection system.

Technical Characteristics

Ten of the eleven models of the Silcraft Whirlpool System and all of the predicate devices consist primarily of the following components: (1) a tub; (2) a shower wand; (3) a control console; (4) a water temperature control; (5) a whirlpool motor; (6) multiple whirlpool jets; and (7) a built-in automatic or manual disinfection system. One models does not have a built-in disinfection system.

Each model of the Silcraft Whirlpool System and all of the predicate devices are labeled for use with one or more patient lift and/or transfer devices, including certain Silcraft transporters and lifts ("the Silcraft Patient Lift"). The

Silcraft Patient Lift and the legally marketed lifts are intended be used to transport patients from the bed to the bath and vice versa and to lift them into and out of the tub. Any minor technological differences between the Silcraft Patient Lifts, most of which are exempt from 510(k) requirements, and legally marketed lifts do not raise any new questions of safety or effectiveness.

The labeling for the models of the Silcraft Whirlpool System that have built-in disinfection systems state that Silcraft Disinfectant should be used to disinfect the devices. This general purpose disinfectant is registered with the Environmental Protection Agency ("EPA"). For this reason, the Silcraft Disinfectant device is substantially equivalent to reference products FDA has on file.

Summary Basis for the Finding of Substantial Equivalence

The safety and effectiveness of the Silcraft Whirlpool System is based on the long history of use of hydrobaths with very similar technological characteristics. The Silcraft Whirlpool System and all of the predicate have the same intended use: bathing and hydromassage. The various models of the Silcraft Whirlpool System also have very similar principles of operation and technological characteristics as the predicate devices. Moreover, the minor technological differences between the Silcraft Whirlpool System and the predicate devices, namely the number of valves on their control consoles, certain components of their disinfection systems and different features of the lifts which they are labeled for use with, do not raise any new questions of safety or effectiveness. Thus, each model of the Silcraft Whirlpool System is substantially equivalent to the predicate devices.

All of the Silcraft Patient Lifts are exempt from 510(k) requirements because they are non-AC-powered lifts. Nevertheless, these patient lifts are substantially equivalent to legally marketed lifts with which the predicate devices are labeled for use because they have the same intended use, similar principles of operation and technological characteristics. Any minor differences in their technological characteristics do not raise any new questions of safety or effectiveness.

~~The EPA-registered Silcraft Disinfectant is substantial equivalent to other general purpose disinfectants by virtue of its EPA registration and compliance with EPA and FDA's Memorandum of Understanding regarding liquid chemical germicides and FDA's guidance documents regarding general purpose disinfectants and hydrobaths.~~



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 26 1998

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

Re: K971592
XTank² 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:

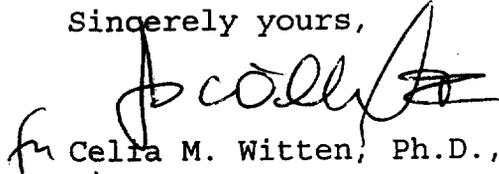
We have reviewed your Section 510(k) notifications of intent to market the devices referenced above and we have determined these devices are substantially equivalent (for the indications for use stated in the enclosures) to devices marketed in interstate commerce prior to May 28, 1976, the enactment 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 (Pre-market 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,



fm 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: Silcraft Whirlpool System

Indications For Use:

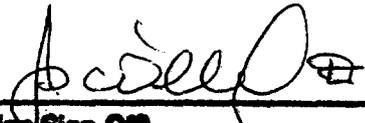
Models 2001, 3700B, 3700D, 3600, and 3600XL: Full immersion bathing and hydromassage of the lower extremities of patients in a sitting position.

Models 2300 and 3300: Full immersion and hydromassage of patients in a sitting position.

Models 4300, 5300, 4400SS, and 5400SS: Full immersion bathing and hydromassage of patients in a reclining position.

(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 2971593

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X

(Optional Format 1-2-96)