JUL - 6 2011 K110994

CHAPTER 5

ARJOHUNTLEIGH

510(k) Summary

1.1 Address of Manufacturing Facilities

Arjo Hospital Equipment AB
Verstadsvägen 5
S-241 21 Eslöv
Sweden
Phone :+46-413-64500
Fax . :+46-413-13876
Establishment Registration: 9611530

1.2 Address of 510(k) Holder Facilities

ArjoHuntleigh, Inc.
2349 West Lake Street, Suite 250 Addison, IL 60101 USA
Phone:+(630) 785-4885
Fax: +(630) 576-5012
Establishment Registration: 1419652

1.2.1 Official Correspondent

Arjo Huntleigh, Inc.
2349 West Lake Street, Suite 250 Addison, IL 60101 USA
Establishment Registration: 1419652
Brenda Ammonette
Sr. Director of Regulatory
Ph: 630.785.4885 800.323.1245, ext. 54885
Fax: 630.576.5012
Brenda.Ammonette@ArjoHuntleigh.com

1.3 Device Classification

Device name:	*Parker Immersion Hydrobath*
Device class:	*II*
Classification Panel:	*Physical Medicine*
Classification Number:	*890.5100*
Product Code:	*ILJ*
Trade/Proprietary Name:	*Arjo or Arjo Huntliegh* followed by *Parker 500*

1.4 Substantially Equivalent to

Parker 500 is substantially equivalent to the following predicate devices:

- Parker 420 (the manufacturer's predecessor device cleared under K964926).
- Century / Saflift (Arjo-Century Inc, cleared under K930665)
- Rhapsody (Arjo Inc, cleared under K001079)
- Whirlpool bathing system (DUTTON-LAINSON CO, cleared under K930624)

1.5 Description of the Device

The bathing system consists of a tub composed of fiberglass, which is covered by a panel containing all the integrated technical controls of the system. The bathing system is offered with or without a tub height positioning system, tub tilt system, hydro massage and an integrated disinfection system. The bathing system is not a sterile device.

1.6 Indications for use

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 removal of contaminated tissue.

1.7 Summary of Comparison Data

Parker 500 uses the same fundamental technology features and safety functionalities as the Parker Bath Systems (K964926), Century/Saflift (K930665), Whirlpool bathing system (K930624) and Rhapsody (K001079). Therefore, it is concluded that there is no significant difference in the basic function, safety and efficacy between the *Parker 500* and the predicate devices.

1.8 Date Summary Prepared

Monday the 7th of March 2011

Brenda Ammonette
Sr. Director of Regulatory
ArjoHuntleigh, Inc., USA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL - 6 2011

ArjoHuntleigh, Inc.
% Ms. Brenda Ammonette
Senior Director of Regulatory
2349 West Lake Street, Suite 250
Addison, Illinois 60101

Re: K110994
Trade/Device Name: Parker 500 Immersion Hydrobath
Regulation Number: 21 CFR 890.5100
Regulation Name: Immersion hydrobath
Regulatory Class: Class II
Product Code: ILJ
Dated: April 08, 2011
Received: April 08, 2011

Dear Ms. Ammonette:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erl Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): Not known

Device Name: **Immersion hydrobath**

Indications for Use:

- 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 removal of contaminated tissue

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110994