510(k) Summary

JUN 11 2010

SPONSOR **807.92(a)(1)**

Company Name:	Clearwater Products LLC
Company Address	5910 Pine Hill Road, Unit 9 Port Richey, FL 34668
Telephone:	(727) 842-1700
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Contact Person:	Robert Bolden

Summary Preparation Date: May 18, 2010

DEVICE NAME **807.92(a)(2)**

Trade Name:	Water Lily™
Common/Usual Name:	Colon Hydrotherapy System
Classification Name:	Colonic Irrigation System
Regulation Number:	876.5220
Product Code:	KPL
Device Class:	Class II
Panel:	Gastroenterology/Urology

PREDICATE DEVICE **807.92(a)(3)**

Legally Marketed Equivalent Device

Company	*Product*	*510(k) #*
Lifestream Purification Systems	Angel of Water Colon Hydrotherapy System	K003720

DEVICE DESCRIPTION **807.92(a)(4)**

The Water Lily™ is a professional colon hydrotherapy system for use when medically indicated. It introduces filtered water at a comfortable temperature into the large intestine, thus cleansing the colon of its contents. Water temperature is controlled by means of a mixing valve; flow is controlled by one switch operated by the user. The system is manually sanitized prior to each use with a suitable broad spectrum disinfectant (not included). The system includes disposable tubing and a sterile, disposable rectal nozzle intended for single use only (ConMed Corporation K050992).

DEVICE INDICATIONS FOR USE **807.92(a)(5)**

The Water Lily™ Colonic Hydrotherapy System is indicated for colon cleansing when medically indicated, such as before radiological or endoscopic examination.

COMPARISON OF TECHNICAL CHARACTERISTICS 807.92(a)(6)

12.3 Predicate Product Comparison Table

Parameters	The Water Lily™	Angel of Water™
510(k) Number		K003720
Indications for Use	The Water Lily™ Colonic Hydrotherapy System is indicated for colon cleansing when medically indicated, such as before radiological or endoscopic examination.	Colon cleansing when medically indicated such as before radiological or endoscopic examination.
Controlled by patient	Yes	Yes
Temperature Range	99°-103° F	99°-103° F
Temperature cannot rise above 103° F	Yes	Yes
Water flow controlled by mixing valve	Yes	Yes
Single-use sterile disposable nozzle	Yes	Yes
Sprayer	Yes	Yes
Filtration:		
Ultraviolet	Yes	Yes
Carbon Filtration	Yes	Yes

NONCLINICAL AND CLINICAL TEST 807.92(b)

Summary of Non-Clinical Testing

Test Parameter	Results
Ensure pressure inside patient's colon will not exceed 2 psi	Formula for PSI-On a gravity fed line is 100 ft. drop = 43 psi. Therefore a 2.5 Ft drop =1.07 psi (.43 x 2.5 = 1.075) Confirmed by 0-3 psi gage
Demonstrate that the device will shut down when the water temperature exceeds 104° F	When water temperature reaches 104°F the controller sets off an **audible alarm and sends a signal to the solenoid valve that closes water flow to the client.** The therapist will cool down the system to 104°F and reset the unit.
Electrical Safety - UV filtration system	Approved by UL and CSA
Electrical safety - Controller-thermocouple and solenoid valve	Approved by UL and CSA

The Angel of Water, K003720 and the Water Lily were compared in the following areas and found to have similar technological characteristics and to be equivalent:

Intended Use
Target Population
Design
Performance
Materials Used
Where Used

SAFETY and EFFECTIVENESS

The Water Lily™ uses the same principles of operation as the Angle of Water™. The water temperature range of 99°-103° is the exact same for both devices. All other aspects of the two devices are simple plumbing using tubes and valves. This 510(k) does not raise any new issues effecting safety and effectiveness.

Biocompatibility and Sterilization:

ConMed rectal nozzle (K050992)

CONCLUSION **807.92(b)(3)**

The Water Lily and the predicate device (Angel of Water K003720) were compared in the following areas and found to have similar technological characteristics and to be equivalent:

Intended Use
Target Population
Design
Performance
Materials Used
Where Used

The Water Lily™ uses the same principles of operation as the Angel of Water™. The water temperature range of 99°-103° is the exact same for both devices. All other aspects of the two devices are simple plumbing using tubes and valves. This 510(k) does not raise any new issues effecting safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G60
Silver Spring, MD 20993-0002

Clearwater Products, LLC
c/o Mr. E. J. Smith
Consultant
Smith Associates
1468 Harwell Avenue
CROFTON MD 21114

JUN 11 2010

Re: K094022
Trade/Device Name: Water Lily™
Regulation Number: 21 CFR §876.5220
Regulation Name: Colonic irrigation system
Regulatory Class: II
Product Code: KPL
Dated: June 7, 2010
Received: June 7, 2010

Dear Mr. Smith:

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,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K094022

Device Name: Water Lily™

Indications for Use:

The Water Lily™ is indicated for colon cleansing when medically indicated, such as before radiological or endoscopic examination.

(Check appropriate designation below)

Prescription Use ___√____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 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 Reproductive, Abdominal, and Radiological Devices
510(k) Number K094022