MAR 2 3 2004

Ultimate Concepts Inc.

7835 South 1300 East
Sandy, Utah 84094
Phone 800-682-3241 or 801-566-3214

SUMMARY

Submitter's name:	Ultimate Concepts, Inc.
Address:	7835 South 1300 East Sandy, Utah 84094
Phone:	800-632-3241
Fax number:	801-566-7152
Name of contact person:	Grace Holland Regulatory Specialists, Inc 3722 Ave. Sausalito Irvine, CA 92606 Phone: 949-262-0411 fax: 949-552-2821
Date the summary was prepared:	September 8, 2003
Name of the device:	Ultimate Professional Continuous Flow Colonic System
Trade or proprietary name:	Ultimate Professional Continuous Flow Colonic System
Common or usual name:	Colonic Irrigation System
Classification name:	Colonic Irrigation System

The legally marketed device to which we are claiming equivalence [807.92(a)(3)]:

Angel of Water, Colon Hydrotherapy System, manufactured by Lifestream Purification Systems. Reference K003720

Description of the device:

This colonic irrigation system is a device intended to instill water into the colon through a nozzle inserted into the rectum to cleanse (evacuate) the contents of the lower colon. The system is designed to allow evacuation of the contents of the colon during the administration of the colonic irrigation. The device consists of a container for fluid connected to the nozzle via tubing and includes a system which enables the temperature, and gravity induced flow of water through the nozzle to be controlled. The device includes a console-type toilet and

necessary fittings to allow the device to be connected to water and sewer pipes. This device uses water that comes from household type hot and cold outlets.

Indications:

This device is intended for colon cleansing when medically indicated, such as before radiological or endoscopic examinations.

Summary of the technological characteristics of our device compared to the predicate device:

The Angel of Water, K003720 and Ultimate Professional Continuous Flow Colonic System were compared in the following areas and found to have similar technological characteristics and to be equivalent.

Intended use
Target Population
Design
Performance
Where Used

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 3 2004

Ultimate Concepts, Inc.
c/o Ms. Grace Holland
Regulatory Consultant
Regulatory Specialists, Inc.
3722 Ave. Sausalito
IRVINE CA 92606

Re: K033149
Trade/Device Name: Ultimate Professional Continuous Flow Colonic System
Regulation Number: 21 CFR §876.5220
Regulation Name: Colonic irrigation system
Regulatory Class: II
Product Code: 76 KPL
Dated: January 29, 2004
Received: February 2, 2004

Dear Ms. Holland:

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.

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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K033149

Device Name: Ultimate Professional Continuous Flow Colonic System

Indications For Use:

This device is intended for colon cleansing when medically indicated, such as before radiological or endoscopic examinations.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

David A. Segura
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K033149