K062811

Life Outcomes, Incorporated
510(k) Premarket Notification

Summary of Safety and Effectiveness

DEC 20 2006

Submitted by:	Life Outcomes, Inc. 5696 Peachtree Parkway, Suite A Norcross, GA 30092 USA Telephone: (770) 622-4427 Facsimile: (770) 622-9021 Website: www.lifeoutcomes.com
Contact Person:	Thomas Taccini Director, Research & Development Westmed, Inc. 109 Inverness Drive East, Suite A Englewood, CO 80112 USA Telephone: (303) 783-0011 ext. 1132 Facsimile: (303) 708-8631 Email: ttaccini@westmedinc.com
Date Prepared:	September 15, 2006
Proprietary Name:	DPILog DPC-512
Common Name:	Accessory to Metered Dose Inhalers
Classification Name:	Anesthesiology 21 CFR 868.5630 73 CAF
Predicate Device:	MedTrac MDILog MDC-512, K990185, cleared April 1, 1999 MedTrac MDILog MDC-511, K970344, cleared August 6, 1997 NewMed Doser, K935955, cleared September 516, 1994

Device Description: The DPILog DPC-512 is comprised of a reusable electronics module and a disposable battery sleeve that snaps together around an already cleared/marketed dry power inhaler. The device utilizes previously cleared/marketed accessories, i.e., an infrared docking station to communicate the collected data to a computer via an interface cable and software. The DPILog System has direct application to physicians involved in clinical trials, disease management and training patients in proper use of DPIs. The objective data collected by the DPILog allows researchers improved quality of information in clinical trials and increased precision of statistical analysis.

Intended Use of Device: The DPILog DPC-512 is intended for use by a single patient under the care or treatment of a physician or licensed healthcare professional. The DPILog is prescribed by the doctor when detailed Dry Powder Inhaler (DPI) usage monitoring is indicated. The DPILog can be used by any patient who regularly uses DPIs as prescribed by a physician.

It will be the physician or healthcare professional's responsibility to contact and coordinate with Life Outcomes to acquire and attach the DPILog electronics module, disposable sleeve bodies onto the DPI actuator. DPIs with attached DPILog electronic modules and disposable sleeve bodies will be distributed to patients by a physician or healthcare professional.

Technological Characteristics: The proposed device is equivalent to the identified predicate devices with respect to technological characteristics and function. The device has been designed to comply with the applicable sections of International Electrotechnical Commission Standards for Medical Devices, IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8 plus International Standards Organization Standards for Risk Management ISO 14971 and Biocompatibility ISO 10993.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 20 2006

Life Outcomes, Incorporated
C/O Mr. Charles M. Hart
Principle Consultant
HART Consulting
3957 Blue Pine Circle
Highlands Ranch, Colorado 80126-8077

Re: K062811
Trade/Device Name: DPILog, Model DPC-512
Regulation Number: 868.5630
Regulation Name: Nebulizer Anesthesiology
Regulatory Class: II
Product Code: CAF
Dated: December 7, 2006
Received: December 8, 2006

Dear Mr. Hart:

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 such 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 (240) 276-0115. 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 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/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K062811

Device Name: DPILog DPC-512

Indications for Use:

The DPILog is intended for use by a single patient under the care or treatment of a physician or licensed healthcare professional. The DPILog is prescribed by the doctor when detailed Dry Powder Inhaler (DPI) usage monitoring is indicated. The DPILog can be used by any patient who regularly uses DPIs as prescribed by a physician.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

...sion-Off)
...of Anesthesiology, General Hospital,
...Control, Dental Devices

...Number K062411

Prescription Use ✓ OR Over-The-Counter ___

(Per 21 CFR 801.109)