DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 8 2006

Caldyne, Incorporated
C/O Mr. Tom Shanks
MD Ventures
29201 Via Norte
Palm Beach Gardens, Florida 33410

Re: K051279
Trade/Device Name: Caldyne, Incorporated Exhalometer EX100, Model EX100
Regulation Number: 21 CFR 868.1850
Regulation Name: Monitoring Spirometer
Regulatory Class: II
Product Code: BZK, CAH
Dated: September 2, 2005
Received: September 6, 2005

Dear Mr. Shanks:

This letter corrects our substantially equivalent letter of September 7, 2005.

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 (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.

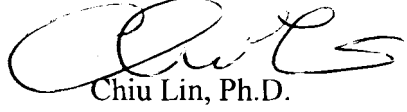
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 continue 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) 276-0120. 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/dsma/dsmamain.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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K051279

Device Name: EXHALOMETER™ EX100

Indications for Use:

The ***EXHALOMETER™ EX100*** is intended to measure the tidal volume, minute volume and respiration rate being delivered to the patient via expiratory ports of resuscitation devices such as transport ventilators and resuscitators. The device is primarily used by Emergency Medical Technicians during emergency transport operations and can also be used for intra-hospital transport. The device is used for indicating how well the resuscitator is functioning. In addition, the device is used for periodically checking the adequacy of the ventilation effort of patients who have initiated spontaneous respiration. The EXHALOMETER can also be used for training and developing resuscitation techniques.

(PLEASE NO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CRDH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K051279

Prescription Use X OR Over-the-Counter Use
(per 21 CFR 801 109) (Optional Format 1-2-96)

K051279
SE 9/7/05

4.0 510(k) SUMMARY

In accordance with 21 CFR section 807.92, CALDYNE, Inc. is submitting the following 510(k) summary:

4.1 Submitter Information:

CALDYNE, Inc.
Contact: Mark Grady, President
2425 Maryland Rd.
Willow Grove, PA 19090
USA
Phone Number: (215) 830-3076

FDA Registration No.: Pending
Owner / Operator No.: Pending

4.2 Preparer of Submission and Contact for Information:

MD Ventures
Tom Shanks*, Principal
29201 Via Norte
Temecula, CA 92591
Telephone: (951) 506-2674 Fax: (951) 506-3040

*Submission contact for correspondence and additional information.

4.3 Name of Device:

Proprietary Name:	CALDYNE Inc.'s EXHALOMETER™ EX100.
Common Name:	Respiratory Monitor or Ventilator Monitor.
Classification Name:	Monitoring Spirometer, [21 CFR 868.1850(a)].
Regulation Number:	21 CFR 868.1850(a) for Monitoring Spirometers.
Product Code:	BZK
Class:	Class II (performance standards)

4.4 Substantial Equivalence:

This submission establishes the substantial equivalence of the CALDYNE, Inc. EXHALOMETER™ EX100 to two predicate devices:

(1) The StarTrack Infant Graphics Monitor, K983274, SE letter: 12/09/98.

(2) The Newport Compass Exhaled Tidal Volume Monitor, K973314, SE letter: 10/25/93.

4.5 Description of the Device:

The ***EXHALOMETER™ EX100*** is a device that is a self contained and internally powered analyzer designed to connect to a specially designed filter assembly, which in turn, connects to the expiratory port of resuscitation devices such as transport ventilators and resuscitators. The device measures exhaled air from the patient and provides data that indicates the tidal volume, minute volume, and respiration rate being delivered to the patient. The patient does not inhale through the device.

This device is primarily used by Emergency Medical Technicians and has been designed to be rugged enough to reliably operate in environments encountered in emergency transport operation, including a wide range of temperatures, shock and vibration and electro-magnetic fields. The device and its parts have been designed with adequate mechanical strength so that when subjected to mechanical stress caused by normal use such as pushing, impact, dropping, and rough handling, the will device function normally and will present no potential safety hazard to the patient.

4.6 Intended Use of the Device:

The ***EXHALOMETER™ EX100*** is intended to measure the tidal volume, minute volume, and respiration rate being delivered to the patient. The device is primarily used by Emergency Medical Technicians during emergency transport operations and can also be used for intra-hospital transport. The device is used for accessing how well the resuscitator is functioning. In addition, the device is used for periodically checking the adequacy of the ventilation effort of patients who have initiated spontaneous respiration. The EXHALOMETER can also be used for training and developing resuscitation techniques.

4.7 Technological Characteristics in Comparison to the Predicates:

The CALDYNE, Inc. EXHALOMETER EX100 is substantial equivalent to the two predicate devices with respect to the following design characteristics and functions:

1. The devices are intended for the measurement and display of the patient's expiratory flow, respiration rate, tidal volume, minute volume, and respiration rate.

2. These devices are used for assessing resuscitator function and adequacy of ventilation efforts.

3. The devices are intended for use in intra-hospital environments and patient transport.

4. The device housing components are fabricated from the same or similar plastic resin materials used in the predicate devices. The devices use front panel LCD screens to display readings, graphics, and values as well as providing visual alarms and messages.

5. The devices use pressure transducers and embedded software (not operator programmable) that contain algorithms for calculating air flow values and rates.

4.8 Conclusions drawn from the Non-Clinical Tests:

Data provided in this submission indicate that the basic functional characteristics of the CALDYNE, Inc. EXHALOMETER EX100 are substantially equivalent to those of the predicate devices. Test data also demonstrates that the device is safe and effective and functions according to its indications for use as well as meeting the requirements of the device's design specifications.

1. The instrument provides expiratory flow measurements (via bar graph) with accuracy of displayed parameters that are within ± 10% of the actual value.

2. The device displays digital exhalation tidal volumes in milliliters accurate within ± 2% of the performance curve.

3. The instrument displays digital expiration minute volumes (amount of gas exhaled during previous one-minute period expressed in Liters) ± 10% of the actual value.

4. The device displays total number of respiration per minute during the previous minute

5. The Filter Attachment was underwent Viral Filtration Efficiency (VFE) testing and demonstrated the Filter Attachment, at an increased challenge, to be %VFE = > 99.83% and thus prevent contamination of the device by bacteria and viruses.

6. The software (which is embedded within the device and not programmable by the user) has been verified to function correctly as designed and to operate the device according to the device design specifications and requirements.

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