MAR 1 0 2009

4.0 510(k) SUMMARY:

In accordance with 21 CFR Section 807.92, DynamiTech Medical, Inc. is submitting the following 510(k) summary:

4.1 Submitter Information:

DynamiTech Medical, Inc.
Company Representative: John Snobarger, President
1307 Suffolk Street
Bakersfield, CA 93312
USA
FDA Registration No.: 3007102815
Owner / Operator No.: 10026476

4.2 Preparer of Submission and Contact for Information:

4.2.1 Solutions MDI, Inc.

Gus Bock, Managing Director
26847 Chamomile Street
Murrieta, CA 92562
Telephone: (909) 641-2203

4.2.2 Keith Lowrey, Partner & Consultant (contact for correspondence and information)
611 South Schoolhouse Creek Rd.
Grants Pass, OR 97526
Telephone: (541) 476-1628 / Cell: (805) 403-6977

4.3 Name of Device:

Proprietary Name:	DynamiPeak™ Peak Flow Meter
Common Name:	Peak Flow Meter.
Classification Name:	Peak Flow Meter for Spirometry.

Regulation Number:	21 CFR 868.1860.
Product Code:	BZH
Class:	Class II (performance standards)

4.4 Substantial Equivalence:

This submission establishes the substantial equivalence of the DynamiTech Medical, Inc. DynamiPeak™ Peak Flow Meter to five predicate devices:

(1) Micro Direct, Inc., MICROPEAK Peak Flow Meter, K030586, SE Date: 08/27/2003.

(2) Monaghan Medical Corp., TRUPEAK Peak Flow Meter, K963095, SE Date: 11/04/1996.

(3) Galemed Corp., GALEMED Peak Flow Meter, Models 3754/3752, SE Date: 04/03/2003.

(4) Monaghan Medical Corp., TRUPEAK Peak Flow Meter, K955234, SE Date: 11/14/1996.

(5) Vitalograph Ltd., PULMONARY MONITOR, K781922, SE Date: 02/13/1979.

4.5 Description of the Device:

The DynamiPeak™ Peak Flow Meter is a simple mechanical device that responds to and indicates the peak expiratory flow rate (PEFR) generated by the user during a forced exhalation maneuver.

The inlet of the device is placed into the user's mouth after which the maximum rate at exhalation is attempted from nearly full lungs. As this forced exhalation commences, and internal piston extends a spring as it reacts to an internal pressure spike. An indicator is pushed by the moving piston and remains at the maximum displacement position of the piston after the maneuver is terminated. This position corresponds to the PEFR and is quantified in liters per minute by reading a scale next to the indicator. The piston displacement function is logarithmic, thereby providing greater resolution of the scale at lower PEFR readings.

DynamiPEAK™

Technical Specifications

Range:	60-900 l/mn
Scale Increment	10 l/mn
Accuracy :	<+/- 10% or 20 l/mn
Repeatability:	<+/- 2%
Calibration:	100% (individual unit)
Frequency Response:	c100Hz @ 350 l/m
Dynamic State:	Critically damped @ 350 l/m
Standard Compliance:	EN 13826:2003
	AS/NZ 4237
	NAEP Guidelines 1991 (ATS)

DynamiPEAK is made from top quality, medical-grade polymers and stainless steel for durability and stability of accuracy.

An ideal, reliable tool for the management, monitoring and assessment of respiratory conditions such as asthma.

DynamiPEAK comes complete with detachable mouthpiece, a one-month peak flow chart, instructions for use and easy to use guide to normal peak flow values.

CE 0482

Manufactured by:
Fyne Dynamics, LTD. for:

DYNAMITECH MEDICAL™

P.O. Box 20097
Bakersfield, CA 93390
www.dynamitechmedical.com
Phone: 661.588.5102

4.6 Intended Use of the Device:

The ***DynamiPeak™ Peak Flow Meter*** is designed as a single-patient use device to measure the Peak Expiratory Flow Rate (PEFR). Device is intended for use by children to Adults.

4.7 Technological Characteristics in Comparison to the Predicates:

The DynamiPeak™ Peak Flow Meter is substantially equivalent to the predicate device, Micro Direct, Inc., MICROPEAK Peak Flow Meter with respect to all of the following design characteristics and functions:

4.7.1 Although labeled differently with their respective "final manufacturer and distributor" names, both the ***DynamiPeak™ Peak Flow Meter*** and the ***MICROPEAK Peak Flow Meter***:

4.7.1.1 Are fabricated by the same contract supplier, Fyne Dynamics, Ltd., a manufacturer of peak flow meters in the UK. Fyne Dynamics, Ltd. manufactures the ***Pinnacle Peak Flow Meter*** (P/N 72000) which is not marketed in the U.S. Both the DynamiPeak™ Peak Flow Meter and the MICROPEAK Peak Flow Meter are substantially equivalent to the Pinnacle Peak Flow Meter.

4.7.1.2 Are assembled from substantially equivalent components.

4.7.1.3 Are assembled from substantially equivalent components fabricated from substantially equivalent raw materials.

4.7.1.4 Have substantially equivalent design specifications which have been validated and verified.

4.7.1.5 Have under gone and have passed substantially equivalent clinical testing criteria.

4.7.2 Both devices are intended for use as a single-patient use device to measure the Peak Expiratory Flow Rate (PEFR) of a patient with Asthma or other lung disease. The PEFR is a recognized value of lung function and changes in PEFR assist patient in managing asthma and lung disease and provides information for patient to reference physician instructions on medication and other actions in plan based on changes.

4.7.3 The devices both function adequately as peak flow meters.

4.7.5 The devices have been demonstrated to function effectively in measuring patients' peak expiratory flow rates

4.7.6 The devices meet the recommendations of the American Thoracic Society's Standardization of Spirometry.

4.8 Conclusions drawn from the Non-Clinical Tests:

Data provided in this submission indicate that the basic functional characteristics of the DynamiPeak™Peak Flow Meter are substantially equivalent to those of the predicate devices.

4.8.1 The DynamiPeak™Peak Flow Meter and the MICROPEAK Peak Flow Meter share the same design specifications, fabricated from the same materials, and are manufactured by the same contract manufacturing supplier.

4.8.2 The DynamiPeak™Peak Flow Meter has the same indications for use as the predicate devices.

4.8.3 The DynamiPeak™Peak Flow Meter and predicate device are both simple mechanical devices that respond to and indicate the peak expiratory flow rate (PEFR) generated by the patient during a forced exhalation maneuver.

4.8.4 The DynamiPeak™Peak Flow Meter and predicate devices are designed with inlets that are placed into the patient's mouth. The patient attempts maximum the maximum rate of exhalation from nearly full lungs. As this forced exhalation commences, an internal piston extends an indicator which is pushed by the moving piston and remains at the piston's maximum displacement position after the exhalation is completed. This position corresponds to the PEFR and is quantified in liters per minute which is indicated by a scale on the side of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 0 2009

DynamiTech Medical, Incorporated
C/o Mr. Keith Lowrey
Partner and Consultant
Solutions MDI, Incorporated
Pacific Northwest Branch
611 South Schoolhouse Creek Road
Grants Pass, Oregon 97526

Re: K082899
Trade/Device Name: DynamicPeak™ Peak Flow Meter
Regulation Number: 21 CFR 868.1860
Regulation Name: Peak-Flow Meter for Spirometry
Regulatory Class: II
Product Code: BZH
Dated: March 3, 2009
Received: March 5, 2009

Dear Mr. Lowrey:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud M.D.

Ginette Y. Michaud, M.D.
Acting 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: K082899

Device Name: DynamiPeak™ Peak Flow Meter

Indications for Use:

The ***DynamiPeak™ Peak Flow Meter*** is designed as a single-patient use device to measure the Peak Expiratory Flow Rate (PEFR). The device is intended for use by children to adults.

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 Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number K082899