

K061731

**510(k) Special Summary  
Medgraphics Ultima System**

SEP - 6 2006

Date of Summary	June 19, 2006
Company Name	Medical Graphics Corporation 350 Oak Grove Parkway St. Paul, MN 55127
Contact Name	Lynn Brosious
Classification name:	73BZLOxygen Uptake Computer
Product Name:	Ultima System
CFR section:	868.1730 Oxygen Uptake Computer
Device Class:	Class IIa

**Predicate Device:** Medgraphics Desktop Diagnostic System with 15% CO<sub>2</sub> Analyzer, K955432 manufactured by Medical Graphics Corporation, 350 Oak Grove Parkway, St. Paul, MN 55127.

**Description:** The Ultima system is a cardiopulmonary exercise system that provides breath by breath measurements of flow, oxygen uptake and carbon dioxide production.

**Intended Use:** Medgraphics Ultima system is intended for medical applications requiring a non-invasive assessment of the cardiopulmonary response to exercise or measurement of energy expenditure using indirect calorimetry.

**Comparison:** Direct comparison with the predicate device was made with acceptable conclusions.

**Discussion:** Laboratory testing of 11 systems has shown the Ultima system to have substantial equivalence in performance and precision to the predicate device. Tandem gas exchange system validator studies performed with the predicate device produced comparative data output with less than 3% variability for VO<sub>2</sub>, VCO<sub>2</sub> and tidal volume.

**Conclusion:** The Medgraphics Ultima system is substantially equivalent to the predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP - 6 2006

Medical Graphics Corp.  
c/o Ms. Lynn Brosious  
Quality and Regulatory Affairs  
350 Oak Grove Parkway  
St. Paul, MN 55127

Re: K061731

Trade Name: MedGraphics Ultima System  
Regulation Number: 21 CFR 868.1730  
Regulation Name: Oxygen Uptake Computer  
Regulatory Class: Class II (two)  
Product Code: BZL  
Dated: August 28, 2006  
Received: August 28, 2006

Dear Ms. Brosious:

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.

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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) 276-0120. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indications for Use**

**510(k) Number ( if known):** K 061731

**Device Name: Medgraphics Ultima System**

**Indications for Use:**

The Ultima system uses the direct measurement of oxygen uptake to objectively and non-invasively assess cardiac and pulmonary function during exercise. The system can be used to screen for early signs of cardiac and pulmonary dysfunction; differentiate heart and lung disease; assess dyspnea complaints; classify patients according to severity of disease as a guide for patient management; establish an optimal exercise prescription and training program; evaluate the efficiency of prescribed therapy.

The Ultima system uses the direct measurement of oxygen uptake and carbon dioxide production to provide nutritional assessment, to optimize nutritional supplements and quantify substrate utilization.

The Ultima system can also provide direct Fick determination of cardiac output using real time oxygen uptake measurements.

Prescription Use   X   AND/OR Over the Counter use         
(Part 21 CFR 801 Subpart D)           (21 CFR 801 Subpart C)

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(Division Sign-Off)  
Division of Cardiovascular Devices  
510(k) Number   K061731