K030464

MAR 1 4 2003

## 510(k) SUMMARY

## Collins Medical, Inc.'s GEM

**Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared**

Collins Medical, Inc.
220 Wood Road
Braintree, MA 02184

Phone: 781-843-0610
Facsimile: 781-843-4024

Contact Person: Donald Henton

Date Prepared: Feb. 10, 2003

**Common or Usual Name** GEM (Gas Exchange Module)

**Classification Name** Spirometer, Diagnostic

**Predicate Devices** Collins CPL - K992743
SensorMedics VMAX - K942211

**Intended Use**

The GEM is intended to be used for diagnostic use in the treatment of pulmonary illnesses with an intended use and indication for use as a configurable, non-invasive pulmonary function tester (PFT) testing system.. The GEM is indicated for use in: pulmonary function testing.

**Technological Characteristics and Substantial Equivalence**

Electrical: A medical grade switching power supply is used that operates on 115-240 VAC 50-60 Hz, at 3.15 Amps.
Weight: 18 lbs., 8.2 Kg
Spirometer: The pneumotach is a single-screen bi-directional device that is used in conjunction with commercially available pressure transducers. Resistance is < 1.4 $cmH_2O/L/Sec$ @ 14 L/Sec. Volume accuracy is +/- 3%, and it is calibrated by using a known volume displacement device 3-liter syringe as a standard.

GemTach
Type: Single screen pressure differential
Linearity: 2%
Resistance: < 0.5 $cmH_2O/L/Sec$ @ 14 L/Sec
Accuracy: +/- 3%
Flow Range: +/- 15 L/Sec

Gas Analyzers: The analyzers consist of a fast-response Infrared analyzer for the measurement of carbon monoxide (CO), carbon dioxide ($CO_2$), and methane ($CH_4$), and an electrochemical sensor for fast-response oxygen ($O_2$) measurement. Calibration is accomplished by setting the span with known gas concentrations. In production, step responses, linearity, noise, and drift parameters are monitored, and the pass/fail criteria are identical to that of the CPL.

Multi-Gas
Type: Infrared
CO, $CH_4$ Range: 0-3000 ppm
$CO_2$ Range: 0-15%
Response: < 100 ms
Sample Rate: 100 Hz
Accuracy: 1%
Linearity: < 1%
Noise < 1% full scale

Oxygen
Type: Electrochemical
Range: 0.1-100% $O_2$
Accuracy: 1%
Response 80 ms

**Conformity to Recognized Standards**

Electrical safety: UL 2601-1, EN 60601-1, IEC 60601-1-1, and CSA 22.2 No. 1
Emissions and Immunity: IEC 60601-1-2
Performance: *ATS American Thoracic Society Standardization of Spirometry 1994 Update, Am J Respir Crit Care Med Vol 152. (1995)*

*ATS American Thoracic Society Single-breath Carbon Monoxide Diffusing Capacity (Transfer Factor) Recommendations for a Standard Technique - 1995 Update, Am J Respir Crit Care Med Vol 152. (1995)*

**Substantial Equivalence**

The Collins GEM has the same intended use and indications, principle of operation, and technological characteristerics. is substantially equivalent in safety and effectiveness to the former marketed predicate devices with respect to its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 4 2003

Mr. Donald Henton
Quality System Manager
Collins Medical Incorporated
220 Wood Road
Braintree, Massachusetts 02184

Re: K030464
Trade/Device Name: Collins GEM
Regulation Number: 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: II
Product Code: BZG
Dated: February 11, 2003
Received: February 12, 2003

Dear Mr. Henton:

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 (301) 594-4646. 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,

Susan Runner, DDS, MA
Interim 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 Form

510(k) Number (if known): K030464

Device Name: GEM (Gas Exchange Module)

Indications for Use: : The Collins GEM (Gas Exchange Module)is a Pulmonary Function Test System. is intended as a configurable, non-invasive pulmonary function tester (PFT). These tests are suitable for both pediatric and adult patient testing. Compatible with the Collins' Body Plethysmograph as an optional module.

This is the same intended use as the previously cleared GS Modular Pulmonary Function Test System and CPL Comprehensive Pulmonary Laboratory.

(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 C.F.R. 801.109)

(Optional Format 1-2-96)

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

510(k) Number K030464