

K030917

MAY 14 2003

510(k) SUMMARY

Collins Medical, Inc.'s EAGLE

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: March 21, 2003

Common or Usual Name EAGLE (Diffusion Spirometer)

Classification Name Spirometer, Diagnostic

Predicate Devices Collins CPL - K992743
Collins GEM - K030464

Intended Use

The EAGLE 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 EAGLE 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: 19 lbs., 8.6 Kg

Spirometer: The pneumotach is a single-screen bi-directional device that is used in conjunction with commercially available pressure transducers. Resistance is $< 1.4 \text{ cmH}_2\text{O/L/Sec @ 14 L/Sec}$. Volume accuracy is $\pm 3\%$, 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: $< 0.5 \text{ cmH}_2\text{O/L/Sec @ 14 L/Sec}$

Accuracy: $\pm 3\%$

Flow Range: $\pm 15 \text{ L/Sec}$

Gas Analyzers: The analyzers consist of a fast-response Infrared analyzer for the measurement of carbon monoxide (CO), carbon dioxide (CO₂), and methane (CH₄), and an electrochemical sensor for fast-response oxygen (O₂) 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 GEM.

Multi-Gas

Type: Infrared

CO, CH₄ Range: 0-3000 ppm

CO₂ Range: 0-15%

Response: $< 100 \text{ ms}$

Sample Rate: 100 Hz

Accuracy: 1%

Linearity: $< 1\%$

Noise $< 1\%$ full scale

Oxygen

Type: Electrochemical

Range: 0.1-100% O₂

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



MAY 14 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Donald Henton
Quality System Manager
Collins Medical, Incorporated
220 Wood Road
Braintree, Massachusetts 02184-2403

Re: K030917
Trade/Device Name: EAGLE
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: II
Product Code: BZG
Dated: April 17, 2003
Received: April 18, 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.

Page 2 – Mr. Henton

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): K030917

Device Name: EAGLE

Indications for Use: The Collins EAGLE (Diffusion Spirometer) is a Pulmonary Function Test System. is intended as a configurable, non-invasive pulmonary function tester (PFT) testing system. These tests are suitable for both pediatric and adult patient testing.

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

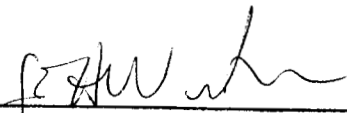
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
Use _____
(Per 21 C.F.R. 801.109)

OR

Over-The-Counter

(Optional Format 1-2-96)



(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K030917