K050381

510(k) Summary
CS Medical Adult TTCF Gas Delivery System

JUL 13 2005

CS Medical, Inc.
6151 Songbird Circle
Boulder, CO 80303
303-817-1789
303-337-5050 fax
James Seiler, CEO

Prepared 7-11-05
L.W. Ward and Associates, Inc.
4655 Kirkwood Court
Boulder, CO 80301
303-530-3279
303-530-4774 fax

Device Name: CS Medical TTCF Gas Delivery System, Class II, 868.5330 BZR

Common Name: Transtracheal Continuous Flow (TTCF) Gas Delivery System

SE Predicate Device: Transtracheal Systems, Inc., TTHF-1000, K981078, 868.5450

Device Description:
The TTCF Gas Delivery System is a gas supply and humidification system mounted on a medical stand. Components include an oxygen blender, a flow meter, pressure relief valve, humidifier, and pressure monitor. A blended source of compressed air and oxygen allow choosing flow rate and F_IO_2 of the mixture. Flows are delivered at 6-15 LPM. Oxygen concentrations are available from 21% to 77%.

Indications for Use:
TTCF is indicated for the treatment of hypoxemia with delivery of transtracheal high flows of a heated and humidified air/oxygen mixture to self-breathing patients with a cuff deflated fenestrated tracheostomy tube. TTCF is indicated for hospital use in adult patients.

Characteristics of proposed versus predicate device:
Both devices have the same indication for use, high flow oxygenation for treatment of hypoxemia in self breathing adult patient populations. Heated and humidified air-oxygen mixtures are the same. Both devices support an open system.

Flow rates are the same at 6-15 LPM delivering oxygen mixture up to 77%

Differences:
The TTHF-1000 is intended for home use and the TTCF for hospital use. The system delivery pressure at the catheter (patient interface) is substantially lower for the TTCF system. The TTCF oxygen supply is facility piped and the predicate from an air compressor.

Non-Clinical Data:

1. Hazard Analysis following ISO 14971demonstrates acceptable and mitigated potential hazards.
2. Electrical safety is demonstrated for the individual components.
3. Effectiveness has been demonstrated for the individual components by previous 510(k) clearance.
4. Plastic materials meet ISO 10993 for biocompatibility.

Conclusion: The TTCF Gas Delivery System is designed, labeled, and verified for performance and safety. The device is substantially equivalent to the legally marketed predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 2005

CS Medical, Incorporated
c/o Lewis Ward
L. W. Ward and Associates, Incorporated
4655 Kirkwood Court
Boulder, Colorado 80301

Re: K050381
Trade/Device Name: Transtracheal Continuous Flow Gas Delivery System
Regulation Number: 21 CFR 868.5330
Regulation Name: Breathing Gas Mixer
Regulatory Class: II
Product Code: BZR
Dated: June 25, 2005
Received: June 27, 2005

Dear Mr. Ward:

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 (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/industry/support/index.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

510(k) Number (if known):

Device Name: Transtracheal Continuous Flow Gas Delivery System

Indications for Use:

TTCF is indicated for the treatment of hypoxemia with delivery of transtracheal high flows of a heated and humidified air/oxygen mixture to self-breathing patients with a cuff deflated fenestrated tracheostomy tube. TTCF is indicated for hospital use in adult patients.

Prescription Use __X__ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K050381