JUL 12 2005

K050379

510(k) Summary
CS Medical Adult TTCF Catheter and Mid Section Hose

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

Prepared 6-9-05
L.W. Ward and Associates, Inc.
4655 Kirkwood Court
Boulder, CO 80301
303-530-3279
303-530-4774 fax

Device Name: Transtracheal Continuous Flow (TTCF) Catheter
Common Name and Classification: Tube, Tracheostomy, Class II, 868.5800 BTO
Predicate Device: Scoop-1 Catheter, Transtracheal Systems, Inc. and Transtracheal Systems, Inc. TTHF-1000 Mid Section Hose

Device Description:
The TTCF Catheter is constructed of clear, latex-free plastics with a radiopaque stripe for identification by x-ray. A rounded tip facilitates insertion and minimizes potential mucous irritation or injury. The catheter is 4 mm O.D. used within an adult Portex Blue Line Fenestrated Tracheostomy Tube. Inner diameter is 3.1 mm in 11.5, 13.5 and 15.5 cm lengths. The distal end is an 11 mm connector capable of attaching to the CS Medical Mid-section Hose. The catheter is supplied sterile and designed as single patient use.

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 devices:
Intended Use: Both the CS Medical and Transtracheal catheters and hose are used for high flow supplemental oxygen for the treatment of hypoxemia. Catheters are available in three lengths. The products are intended for use in open systems.

Flow rates are comparable at 6-12 LPM for the Transtracheal and 6-15 LPM for the CS Medical device.

Both products are designed for adults.

Both catheters have radiopaque stripes used for location during x-ray. Catheters are sold sterile.

Differences:
1. The TTCF catheter is introduced via tracheostomy tube where the SCOOP-1 Catheter is introduced via a tracheocutaneous fistulous tract.
2. The TTCF Catheter has a standard 15 mm tracheostomy tube connector where the SCOOP-1 Catheter attaches to the neck via a flange and securing necklace.
3. The TTCF Catheter connects to the TTCF Gas Delivery System via an 11 mm connector and the SCOOP-1 Catheter connector attaches to the Gas Delivery System via a standard female luer connector.
4. Recommended use for the TTCF Catheter is limited to 24 hours to prevent mucous build-up, reduce infection possibilities, and promote general hygiene in hospital patients versus longer periods for the predicate which is intended for use in the home.

Non-Clinical Data:
1. Materials meet ISO 10993 for biocompatibility.
2. Flow rates are comparable to the predicate and accurate.
3. Hazard Analysis following ISO 14971 demonstrates acceptable and mitigated potential hazards.
4. The catheter is designed, labeled, and verified for performance and safety.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2005

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

Re: K050379
Trade/Device Name: Transtracheal Continuous Flow Catheter
Regulation Number: 21 CFR 868.5800
Regulation Name: Tracheostomy tube and tube cuff
Regulatory Class: II
Product Code: BTO
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 Catheter

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: K050379