K052125

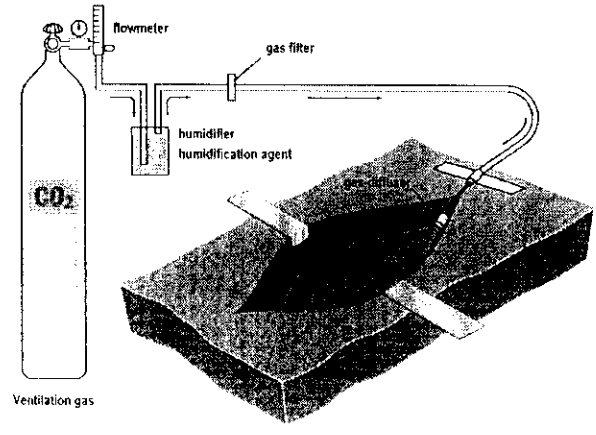
FEB 8 2006

510K(k) SUMMARY

SUBMITTER:	**Cardia Innovation AB** **Lillskogsv 22** **S-133 34 Saltsjobaden** **Stockholm, Sweden**
DATE PREPARED:	**July 27th, 2005**
DEVICE NAME:	**CarbonAid™ gas diffuser**
CLASSIFICATION NAME:	**Carbon Dioxide Gas Insufflator**
PREDICATE DEVICE:	**Pall Medical Laparoshield Conditioned Insufflation Set; K030469**

Device Description:

The CarbonAid™ gas diffuser is a disposable surgical device for effective insufflation of carbon dioxide (CO_2) into an open surgical wound to create a topical atmosphere of 100% CO_2. The larger tube transports the gas from the gas source/humidifier to the surgical wound and has the standard width of medical tubes for this purpose (¼ inch). The hydrophobic gas filter (≤0.2µm) prevents cross-contamination between the gas source/humidifier and the wound. The thinner tube contains a stainless steel wire and stabilizes the gas diffuser inside the wound. The gas diffuser is made of medical foam plastic (with open cells, 30 kg/m^3) that is connected to the thin tube via a plastic disc



Predicate Devices:

There has been a device previously cleared by the FDA in the following 510(K) Notification indicated for use by general surgeons in laparoscopic procedures to provide a path for the insufflation gas from the insufflation device to the patient.

Table 1.
Predicate Device

Device	510(k) Document Number	Date Cleared	Indications
Pall Medical Laparoshield Conditioned Insufflator Set	K030469	5/09/2003	Use by general surgeons in laparoscopic procedures to provide a path for the insufflation gas from the insufflation device to the patient

Intended Use:

Indications:

The CarbonAid™ gas diffuser is intended for use by cardiovascular surgeons in open heart surgery procedures for the insufflation of carbon dioxide gas into the thoracic cavity to reduce the risk of air embolism.

Technological Characteristics:

Technologically, both the new device and the predicate device are the same (i.e. both are intended for the insufflation of carbon dioxide gas. Any differences between the two devices do not raise new questions of safety and effectiveness

Performance Data:

Sufficient data has been gathered from testing to assess that the CarbonAid gas diffuser performs as clinically intended

Conclusions:

Based on the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the device is substantially equivalent to the existing legally marketed device under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 8 2006

Cardia Innovation AB
c/o Jeffrey R. Shideman, Ph.D.
President
7307 Glochester Drive
Edina, MN 55435

Re: K052125
CarbonAid™ Gas Diffuser
Regulation Number: 21 CFR 870.1730
Regulation Name: Laparoscopic Insufflator
Regulatory Class: Class II (Two)
Product Code: HIF
Dated: December 25, 2005
Received: January 10, 2006

Dear Dr. Shideman:

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,

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): K052125

Device Name: CarbonAid™ gas diffuser

Indications for Use:

The CarbonAid™ gas diffuser is intended for use by cardiovascular surgeons in open heart surgery procedures for the insufflation of carbon dioxide gas into the thoracic cavity to reduce the risk of air embolism.

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K052125

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)