

**510(k) SUMMARY**

THIS SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION IS BEING SUBMITTED IN ACCORDANCE WITH THE REQUIREMENTS OF THE SAFE MEDICAL DEVICE ACT OF 1990.

510(k) Summary of Safety and Effectiveness  
CPRotector 2000 Mouth-to-Mouth Barrier

JUL 21 1997

Submitted by: Certified Safety Manufacturing, Inc.  
1400 Chestnut  
Kansas City, MO. 64127  
(816) 483-9090  
FAX (800) 854-9091

Contact: Howard Gerson, Vice-President  
Date Prepared: May 5, 1997  
Trade Name: CPRotector 2000 Mouth-to-Mouth Barrier  
Common Name: CPR Assist Valve

Classification Name: CPR Assist Valves are classified as Class II medical devices, and are listed in 21 CFR 868.5870 as non-rebreathing valves.

The CPRotector 2000 Mouth-to-Mouth Barrier is substantially equivalent to our original CPRotector product which was found to be substantially equivalent by FDA in January, 1994, under K934821.

The CPRotector 2000 device is a mouth-to-mouth barrier that offers protection to the CPR administrator from vomitus and other oral secretions. It is to be used only by persons trained in the application of CPR. Each CPRotector 2000 comes prepackaged with complete instructions for use. It is labeled as a single-use device and therefore must be disposed of after each use, in accordance with applicable rules and regulations.

The CPRotector 2000 includes a one-way valve that directs the breathing gas flow from the CPR administrator to the patient, and directs the exhaled gases away from the rescuer and into the atmosphere. The components used in the manufacture of this device are made from PVC compounds which have been tested to meet the requirements of USP XXII, 1990, and Supplement 5, 1991, for the Biological Test for Plastics, Class VI-70°C.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Howard Freedman  
Certified Safety Manufacturing, Inc.  
1400 Chestnut  
Kansas City, Missouri 64127

JUL 21 1997

Re: K960587  
CPRotector 2000 (CPR Assist Device)  
Regulatory Class: II (two)  
Product Code: 73 CBP  
Dated: May 5, 1997  
Received: May 7, 1997

Dear Mr. Freedman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

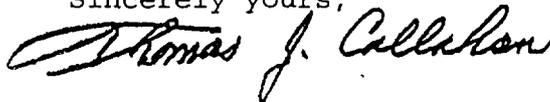
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular,  
Respiratory, and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

*Attachment D*

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510(k) #: K960587

Device Name: CPRotector 2000

Manufacturer: Certified Safety Manufacturing

Indications for use:

A physical barrier for mouth to mouth resuscitation between the victim (patient) and the rescuer. This device makes no "guarantee" of disease protection, but it is designed to help protect the rescuer against potentially contaminated secretions and back drafts emanating from the victim while eliminating actual mouth to mouth contact. This device is to be used only by persons trained in CPR and the use of this device. **DO NOT USE THIS DEVICE ON INFANTS.**

*[Handwritten Signature]*  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
510(k) Number \_\_\_\_\_