

JUL 16 1998

plasco, inc.

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510(k) Summary

K980066

Submitted By and Contact Person:

Gary S. Botsford
4080 Morrison Dr.
Gurnee, IL 60031
847-662-4400 Ext. 218 Fax: 847-662-1084

Date Prepared: 1/5/98

Name of Device:

Proprietary Name: CPR FILTERSHIELD™
Classification Name: Ventilator, Emergency, Manual (868.5915)
Common/Usual Name: FACE SHIELD

Equivalent device:

Laerdal Resusci™ Face Shield 46 00 01 (K880450)

Device description:

The configuration of this device is a plastic PVC sheet with a hole in the center. Sealed around the hole is two plastic molded supports. An electret fibrous media filter is sealed to the proximal molded support.

Device use:

The CPR FILTERSHIELD is a highly portable, single use, physical barrier for use in performing mouth-to mouth resuscitation on adults and children by personnel train in CPR techniques.

The CPR FILTERSHIELD performs the same function and is technologically equivalent to the Laerdal Resusci™ Face Shield. The CPR FILTERSHIELD was found equivalent to the Laerdal shield for the following:

FLOW RESISTANCE
EFFECTS OF TEMPERATURE
BARRIER EFFECTIVENESS

The material compounds used for the patient/rescuer contact components comply with ISO 10993 -1 1992 Biological evaluation of medical devices (surface device, mucosal membrane, contact duration A).



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Gary S. Botsford
Plasco, Inc.
4080 Morrison Drive
Gurnee, IL 60031

Re: K980066
CPR Filtershield
Regulatory Class: II (two)
Product Code: 73 BTM
Dated: April 22, 1998
Received: April 23, 1998

Dear Mr. Botsford:

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 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). 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.

Page 2 - Mr. Gary S. Botsford

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/dsma/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

Section 5 - Statement Of Indications For Use"

The CPR FILTERSHIELD is a highly portable, single use, physical barrier for use in performing mouth-to-mouth resuscitation on adults and children by personnel train in CPR techniques.

Prescription use _____ or Over-the-Counter use

Jack Madon

7-15-98

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K980066