DEC 2 2 2005

K052743

510(K) SUMMARY

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

Submitter	Dynarex Corporation 10 Glenshaw Street Orangeburg, NY 10962 USA Phone: 845-365-8200 Fax: 845-365-8201
Contact Person	James Hurlman
Date of Summary	09-29-2005
Trade Name	CPR Shield with One Way Valve and Barrier Filter, Model 4921
Common Name	Valve, Nonrebreathing
Classification Name	Valve, Nonrebreathing Div. of Anesthesiology, (21 CFR 868.5870) Class II
Predicate Device	4-02 Jr. (CPR Mouth Barrier), Eagle Health Supplies 510(k) #: K945177
Device Description/ Comparison	Dynarex CPR Shield with One Way Valve and Barrier Filter, Model 4921
Intended Use	The Dynarex CPR Shield with One Way Valve and Barrier Filter, Model 492. Intended use is a device used as a physical barrier for mouth to mouth resuscitation.

510(K) SUMMARY

Table of Comparison

Characteristic	Dynarex CPR Shield	Eagle Health Supply 4-02 Jr
Mouthpiece Housing Material	Polystyrene	Polystyrene
Mouthpiece Filter Material	Polypropylene, 70g	Similar
Mouthpiece Gasket Material	Rubber, Latex Free	Similar
Protective Face Shield	PVC	PVC
Sterility	Non Sterile	Non Sterile
Packaging	Sealed Polyethylene Bag	Similar

The CPR Shield with One Way Valve and Barrier Filter, Model 4921 is a mouth to mouth barrier that offers protection to the person performing CPR to a patient from vomitus and oral secretions. The device is to be used by persons trained in CPR techniques. The device comes prepackaged with instructions for use. It is labeled as a single use device and should be disposed of after one use.

The CPR Shield 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 on the Dynarex CPR Shield with One Way Valve and Barrier Filter are equivalent to the predicate devices.

The biocompatibility testing has been successfully performed to FDA recognized standards for Cytotoxicity, Skin Irritation and Skin Sensitization. The finished device has been tested to all applicable portions of ASTM F920-93. Additional testing to ASTM D6499-00 Inhibition ELISA was also conducted and found to be acceptable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 2 2005

Mr. James Hurlman
Manager, Quality Assurance & Regulatory Affairs
Dynarex Corporation
10 Glenshaw Street
Orangeburg, New Jersey 10962

Re: K052743
Trade/Device Name: Dynarex CPR Face Shield with One Way Valve and Barrier Filter
Regulation Number: 868.5870
Regulation Name: Nonrebreathing Valve
Regulatory Class: II
Product Code: CBP
Dated: September 29, 2005
Received: October 3, 2005

Dear Mr. Hurlman:

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.

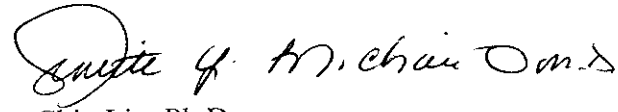
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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): K052743

Device Name: Dynarex CPR Face Shield with One Way Valve and Barrier Filter

Indications For Use:

This device is used as a physical barrier for mouth to mouth resuscitation

The use of this device does not guarantee complete protection from disease transmission.

Prescription Use ✓ (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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