K963848

BriGam Post Office Box 1009 Morganton, N.C. 28680-1009 TEL. 704-437-0236
FAX. 704-437-7695

510(k) Summary for K963848

JUL - 7 1997

Submitter's Name: Bill Brooks
Address: 65 Hanes Road
Newland, NC 28657
Phone #: (704) 733-8121
FAX: (704) 733-8741
Contact Person: Bill Brooks
Date Summary Prepared: 12/17/96

Proprietary Name: Manual Resuscitator
Common Name: Manual Emergency Ventilator
Classification Name: Manual Emergency Ventilator
(per CFR section 868.5915)

Marketed Device to Whom we are claiming equivalence:

Our device is substantially equivalent to the currently marketed device by Mercury (Mercury® CPR Bag) Medical and Ambu® (Ambu Spur® Resuscitator) Inc.

Description of the Device:

The device is a disposable, single patient use manual resuscitator that includes a compression bag, intake and patient valve, and a closed vinyl oxygen reservoir bag, (options: open corrugated tubing or open expandable tubing in lieu of closed vinyl oxygen reservoir bag), and an optional peep valve and/or face mask.

Intended Use: The intended use for this device is to provide emergency respiratory support for Adult, Child and Infant.

Technological Characteristics of our device compared to the predicate device:

The technological characteristics of Owens-BriGam Manual Resuscitator are substantial equivalent to Mercury Medical and Ambu Inc. Medical Resuscitator. BriGam's Manual Resuscitator is of generally the same form and intended to be used in the same manner as the substantially equivalent products as outlined in Exhibit E.

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Test Summary:
The resuscitator does not come in direct contact with the patient, although the following tests were performed on the vinyl compression bag, rubber reservoir bag and the silicone rubber lip valve.

	Item	Test
A.	Rubber Compression Bag	1. Cytotoxicity 2. Physiochemical (Elastomeric Closures) 3. ASTM Protein Analysis
B.	Vinyl Reservoir Bag	1. Cytotoxicity 2. Physiochemical (Elastomeric Closures)
C.	Silicone Rubber Lip Valve	1. Cytotoxicity 2. Physiochemical (Elastomeric Closures) 3. ASTM Protein Analysis

The scoring (reactivity) for cytotoxicity of item A was noted as "slight" cytotoxic and items B and C noted as "none" cytotoxic. In addition physiochemical tests were performed for items A, B, and C to determine pertinent physiochemical extraction characteristics.

ASTM Protein analysis was performed on items A and C and the results were <50 ug of protein per gram of material.

BriGam Medical Co. believes that this information and referred exhibits and attachments to be sufficient for the FDA to find our proposed device substantially equivalent to other products currently in distribution.

Bill Brooks
Regulatory Affairs/Quality Assurance Director
Official Correspondent
BriGam Medical Co.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 7 1997

Mr. Bill Brooks
Owens-BriGam Medical Company
Post Office Box 1009
Morganton, North Carolina 28680-1009

Re: K963848
Manual Resuscitator
Regulatory Class: II (two)
Product Code: 73 BTM
Dated: May 12, 1997
Received: May 15, 1997

Dear Mr. Brooks:

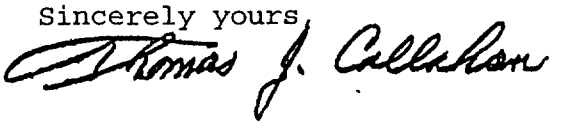
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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.

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

510(k) Number (if known): K963848

Device Name: Manual Resuscitator

Indications For Use:

The intended use for this device is to provide emergency respiratory support for Adult, child and Infant.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jo H. Westerdahl

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices

510(k) Number _____

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)