Datex Engstrom

K970991

Non-Confidential Summary of Safety and Effectiveness

JUN 16

March 12, 1997

Datex Engstrom AB
Box 20109
S-16102 Bromma SWEDEN

Tel - 011-46-8-629-3100 Fax - 011-46-8-298418

Official Contact:	Arne Salo, President
Proprietary or Trade Name:	Datex Engstrom reusable manual resuscitator
Common/Usual Name:	Manual resuscitator
Classification Name:	Ventilator, Emergency, Manual (Resuscitator)
Device:	Datex Engstrom Reusable Manual Resuscitator
Predicate Devices:	Hudson RCI - Durable Manual resuscitator - K895589
	Hudson RCI - PEEP valves - K902062

Device Description:

The Datex Engstrom manual resuscitator is designed for use as an adjunct to artificial respiration and CPR. It can be used to ventilate the apnoeic patient and to augment ventilation and / or oxygen delivery to the spontaneously breathing patient.

Indicated Use --	Provide assisted ventilation
Environment of Use --	Emergency medical services, hospital, patient transport,
Operating	Room (OR), and where assisted ventilation may be required.
Patient population --	Adult, child and infant

Comparison to Predicate Devices:

Attribute	Datex-Engstrom	Hudson RCI
Use		
Intended for use an adjunct to artificial respiration and CPR	Yes	Yes
Can be used to ventilate apnoeic patients	Yes	Yes
Augment ventilation and / or oxygen delivery to spontaneously breathing patients	Yes	Yes
Environment of use - Hospital, OR, anesthesia, PACU, ICU, transport, EMS, where assisted ventilation may be required or needed	Yes	Yes
Intended for use by qualified medical and emergency personnel trained in pulmonary ventilation and advanced cardiac life support techniques	Yes	Yes
Indicated for cleaning and reuse	Yes	Yes
Indicated population - adult, child, infant	Yes	Yes
Design / Theory of Operation		
Connects to a Face mask or endotracheal tube	Yes	Yes
Has four major components Rebreathing valve, Silicone bag, Reservoir valve, Oxygen reservoir	Yes	Yes
May incorporate a PEEP valve	Yes	Yes
Available is three (3) sizes	Yes	Yes
Has available oxygen reservoir	Yes	Yes

Attribute	Datex-Engstrom	Hudson RCI
Design / Theory of Operation		
Fits to standard 15 / 22 mm patient end fittings	Yes	Yes
Offered with standard reusable face mask - various styles	Yes	Yes
May be taken apart and cleaned	Yes	Yes
Cleaning methods - autoclave, EtO	Yes	Yes
Materials		
Bag and duckbill valve - silicone	Yes	Yes
Patient connector, housing parts made of Polysulfone	Yes	Yes
Pop-off valve - aluminum	Yes	Yes
PEEP valve spring stainless steel	Yes	Yes
Face mask - silicone or PVC	Yes	Yes
Reservoir bag - PVC	Yes	Yes
Performance Standards / Specifications		
Patient fittings - 15 / 22 mm ASTM 1054 / ISO 5356	Yes	Yes
Meets all specifications, testing and requirements of ASTM 920 / ISO 8382	Yes	Yes

Differences between Other Legally Marketed Predicate Devices

There is no differences between the intended device and the predicate devices which would be significant to patient safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 16 1997

Mr. Paul Dryden
Datex Engstrom AB
c/o ProMedic, Inc.
6329 W. Waterview Court
McCordsville, Indiana 46055-9501

Re: K970991
Datex-Engstrom Medical Reusable Manual Resuscitator
Regulatory Class: II (two)
Product Code: 73 BTM
Dated: March 13, 1997
Received: March 19, 1997

Dear Mr. Dryden:

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 the 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,

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

Enclosure

JUN 16 1997

SECTION 3
INDICATIONS FOR USE

Pursuant to the Notice of February 6, 1996 regarding listing of Indications for Use on a separate sheet, the following is per that request.

510(k) Number: K970991 (To be assigned)

Device Name: Reusable Manual Resuscitator

Intended Use : To ventilate the apnoeic patient and to augment ventilation and / or oxygen delivery to the spontaneously breathing patient. For use as an adjunct to artificial respiration and cardiopulmonary resuscitation.

Environment of use: Hospital - Emergency Medical Services, Operating Room, during patient transport, Intensive Care Units, where patient assisted ventilation may be administered or required.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Christy Foreman

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K970991

Prescription Use √ **or** **Over-the-counter use** __
(Per CFR 801.109)