K023354

SEP - 5 2003

510(K) Summary
as required by section 807.92(c)
1 October 2002

F.1 Subscribers Name & Address:

Siemens-Elema AB
Electromedical Systems Division, Life Support Systems
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Official Correspondent: Richard Flynn,
(Manager Regulatory Affairs/Quality Assurance, Siemens Medical Solutions USA, Inc. /S.S.G. –R.A. 16 Electronics Avenue Danvers, MA USA 01923)

Contact Person for this submission: Veronica Ekström

F.2 Trade Name:

Device name: Compressor Mini

Common Name	Classification Number	Class	Regulation Number
Compressor Mini	BTI	II	21.CFR.868.6250

F.3 Predicate Device Identification:

Compressor Mini is a first time application. Substantial equivalence to a predicate device, ALRECO 40400 Allan Rehnström AB K951926, is claimed.

F.4 Device Description:

Compressor Mini will provide a supply of dry and filtered compressed air for a medical respiratory ventilator or anaesthesia machine that meets the specifications of the Compressor Mini. Its capacity is approximately 30 l/min at 50-64 psi (350 – 450 kPa).
The compressor is of light weight and compact design. It runs quietly, which makes it suitable for bedside use.
It may be employed as a primary or secondary source of compressed air. The Standby function assures that if the central gas supply fails the Compressor Mini will start to deliver compressed air.
The Compressor Mini is fitted with two alarm parameters, temperature and pressure.
The Compressor Mini is designed with the similar materials and technology as the predicate device ALRECO 40400.

F.5 Intended Use of the Device:

The intended use of Compressor Mini is to provide a supply of dry, filtered, compressed air for a medical respiratory ventilator or anaesthesia machine that meets the specifications of the Compressor Mini. Its capacity is approximately 30 l/min at 50-64 psi (350 – 450 kPa). Compressor Mini is intended to be operated by healthcare providers, physicians, nurses and technicians. Compressor Mini is to be used only for bedside application within the hospital environment. Compressor Mini is neither intended nor suitable for use during in-hospital patient transportation or during ambulance or air transportation. Compressor mini is not suitable for use with MRI.

F.6 Summary of technological characteristics of Device and Predicate Device

The functionality for the Compressor mini is equivalent to the ALRECO 40400.
Compressor mini and ALRECO 40400 have the same technological characteristics, intended use, materials, method of operation, performance claims and energy source but the compressor mini is scaled down for smaller size.
The differences are:

- A more compact design and lighter weight.
- Less power consumption.
- Lower continuous flow and smaller built-in reservoir, since the Compressor Mini is designed to supply only one ventilator with compressed air. The Compressor Compact could support multiple ventilators.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 2003

Siemens-Elema AB
C/O Mr. Timothy W. Capehart
Siemens Medical Solutions USA, Incorporated
16 Electronics Avenue
Danvers, Massachusetts 01923

Re: K023354
Trade Name: Compressor Mini, 115 V, Model 64 81 779 EH81E
Regulation Number: 868.6250
Regulation Name: Compressor, Air, Portable
Regulatory Class: II
Product Code: BTI
Dated: August 8, 2003
Received: August 15, 2003

Dear Mr. Capehart:

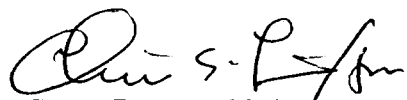
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (301) 594-4646. 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/dsma/dsmamain.html

Sincerely yours



Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K023354

Device Name: Compressor Mini

Indications For Use:

The intended use of Compressor Mini is to provide a supply of dry, filtered, compressed air for a medical respiratory ventilator or anaesthesia machine that meets the specifications of the Compressor Mini. Its capacity is approximately 30 l/min at 50-64 psi (350 – 450 kPa, 3.5 – 4.5 bar). Compressor Mini is intended to be operated by healthcare providers, physicians, nurses and technicians. Compressor Mini is intended to be used for bedside application in a hospital environment. Compressor Mini is not intended to be used during in-hospital transportation or during ambulance or air transportation.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____

(21 CFR 868.6250)

E Jantsch for JXH

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

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