K982789

OCT 29 1998

Dräger

file: 510kstate.RTF
Date: Feb. 1998
Author: Frank Clanzett

510(k) SUMMARY
Summary of Safety and Effectiveness

APPLICANTS NAME AND ADDRESS:
Drager Inc.
Critical Care Systems
3136 Quarry Road
Telford , PA 18969

APPLICANTS TELEPHONE NUMBER:
(215)-721-6917

APPLICANTS FACSIMILE NUMBER:
(215)-721-6915

APPLICANTS CONTACT PERSON:
Harald Kneuer
Regulatory Affairs Manager

DATE THE SUMMARY WAS PREPARED:
MArch, 1998

DEVICE NAME:

Trade Name:	Medical Air Compressor „Model 98"
Common Name:	Medical Air Compressor
Classification Name:	Compressor, Air, Protable (per 21CFR868.6250)
Product Code:	73 BTI

LEGALLY MARKETED DEVICE TO WHICH DRÄGER IS CLAIMING SUBSTANTIAL EQUIVALENCE:

Dräger Medical Air Compressor- Manufactured by Dräger Medizintechnik GmbH, Lübeck, Germany and sold in the United States by Dräger, Inc.

Dräger

DESCRIPTION OF THE DEVICE

The device is electric and produces compressed air from the normal environment to supply compressed air for medical ventilators.

INTENDED USE OF THE DEVICE

The device is an air compressor supplying compressed air for medical ventilators.

COMPARISON OF THE DEVICES

Specification	Medical Air Compressor (K 951126)	*Medical Air Compressor Modell 98*
Intended use	Air compressor supplying compressed air for medical respirators	Air compressor supplying compressed air for medical respirators
Safety:		
High temperature alarm?	Yes	Yes
Audible alarm?	Yes	Yes
Visible alarm?	Yes	Yes
Main Fuses?	Yes	Yes
Performance characteristics		
Dew point depression: below room temperature?	Yes	Yes
Air quality: Dust and oil free?	Yes	Yes
Installed filter?	Yes	Yes
Standby-Mode?	Yes	Yes
Operating Characteristics	All operating characteristics of both devises are substantial equivalent	

Dräger

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICES:

The compressor functions of the Dräger Medical Air Compressor „ Model 98" is substantial equivalent to the predicate device Dräger Medical Air Compressor.

The „Model 98" integrates the same functions and performances that are presently performed by the predicate Dräger Medical Air Compressor.

The „Model 98" fulfils the same standards as the Dräger Medical Air Compressor.

Therefore the device under review is substantial equivalent to the predicate devices concerning safety, efficiency and the intended use.

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Frank Clanzett
Regulatory Affairs
Dräger Medizintechnik

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 29 1998

Mr. Harald Kneuer
Drager, Inc.
Critical Care Systems
3136 Quarry Road
Telford, PA 18969

Re: K982789
Medical Air Compressor, Model #8413419
Regulatory Class: II (two)
Product Code: 73 BTI
Dated: August 7, 1998
Received: August 10, 1998

Dear Mr. Kneuer:

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.

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

Intended Use Statement
of the Dräger Medical Air Compressor Model 98

Air compressor supplying compressed air for medical ventilators.

R. Degenhart

Rainer Degenhart
(project manager)

May 1998

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark Kramer

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K982789

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

(Optional Format 1-2-96)