JAN 2 1 2003

VII. 510(k) Summary

In accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title of the Code of Federal Regulations Part 807 (21 CFR §807), and in particular §807.92, the following summary of safety and effectiveness information is provided:

A. Submitted by

Laetitia Bernard
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Temecula, CA 92592
Telephone: (909) 695-5474

Authorized Regulatory Agent for:
Vygon, S.A.
5-11, Rue Adeline
95440 Ecouen
France
Telephone: (33) 1 39 92 63 63
Contact: Michel Hanania, Regulatory Affairs/Quality Assurance Manager
Date Prepared: November 21, 2001.

B. Device Name

Trade or Proprietary Name: *Boussignac® C.P.A.P Device*

Common or Usual Name: Flow Generator/ PEEP Valve

Classification Name: Positive end expiratory pressure breathing attachment

C. Predicate Devices

The subject device is substantially equivalent to the Vital Signs® Down Adjustable Flow Generator and PEEP valves (K904874, K831503), and to the Caradyne™ Whisperflow™ Flow Generator and PEEP Valves (K982283).

D. Device Description

The *Boussignac® C.P.A.P. Device* is a sterile, single-use, respiratory aid device intended for use with a facemask and gas-supplying device to elevate pressure in a patient's lung. Alternatively, the device may be used in conjunction with an endotracheal tube (via a specific Vygon adapter) to generate and maintain constant positive airway pressure during standard intubation procedures.

The upper, or proximal, port of the device may be connected to a gas-supplying source via an attached connecting tube, while the lower, or distal port may provide for C.P.A.P. pressure monitoring, O_2 monitoring, or an additional source of oxygen in the event that the gas administered to the patient via the proximal connection is air not enriched with oxygen.

E. Intended Use

The *Boussignac® C.P.A.P. Device* is intended to provide CPAP to spontaneously breathing patients in the hospital and pre-hospital environment.

F. Comparison to Predicate Devices

Information provided in this submission has demonstrated that the subject device is substantially equivalent to its predicate devices in terms of design, materials of composition, indications for use, performance, and function.

G. Summary of Non-Clinical Tests

A number of tests were completed to provide data supportive of the device's equivalence to other currently marketed CPAP devices in providing effective CPAP, and data supportive of the specifications identified in the device's labeling. These tests included the following:

- Data demonstrating that pressure decrease with inhalation and the pressure increase with exhalation are not excessive;
- Data demonstrating that pressure decrease with inhalation and the pressure increase with exhalation are not excessive, when an adult bronchoscope is introduced into the device's free-air end.

H. Summary of Clinical Tests

(Not Applicable).

I. Conclusions of Non-Clinical and Clinical Tests

- Pressure decrease with inhalation and the pressure increase with exhalation are not excessive;
- Pressure decrease with inhalation and the pressure increase with exhalation are not excessive, when an adult bronchoscope is introduced into the device's free-air end.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 21 2003

Vygon S A
C/O Ms. Laetitia Bernard
Excaelia
45900 Parsippany Court
Temecula, California 92592

Re: K013884
Trade/Device Name: Boussignac® C.P.A.P. Device
Regulation Number: 868.5965
Regulation Name: Positive End Expiratory Pressure Breathing Attachment
Regulatory Class: II
Product Code: BYE
Dated: December 11, 2002
Received: December 12, 2002

Dear Mr. Bernard:

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

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

V. Draft Labeling

A. Indications for Use

510(k) Number (if known): K013884

Device Name: *Boussignac® C.P.A.P. Device*

Indications for Use:

The *Boussignac® C.P.A.P. Device* is intended to provide CPAP to spontaneously breathing patients in the hospital and pre-hospital environment.

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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

510(k) Number K013884