K023494

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Nellcor

FEB 0 7 2003

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510(k) Summary

Submitted by:	Nellcor Puritan Bennett, Incorporated 4280 Hacienda Drive Pleasanton, CA 94588
Company Contact:	Gina To Senior Regulatory Affairs Project Manager (925) 463-4427 (925) 463-4020 – FAX
Date Summary Prepared:	February 5, 2003
Trade Name:	Nellcor INdGO Manual Resuscitator
Common/Usual Name:	Disposable Manual Resuscitator
Classification Name:	Manual Emergency Ventilator, BTM per 21CFR§868.5915
Legally Marketed (Unmodified) Devices:	DMR^2Plus^{TM} Disposable Manual Resuscitator with Integrated CO_2 Detection, Nellcor Puritan Bennett, Inc. 510(k) # K973419

Device Description

Nellcor INdGO Manual Resuscitator is a bag-valve-mask device with the capability of delivering supplemental oxygen. During artificial ventilation, the resuscitator can be operated from ambient air or provide oxygen-enriched air by connecting the supply tubing to a metered oxygen source.

The Nellcor INdGO Manual Resuscitator is available with and without integrated breath-to-breath CO_2 detection. The integrated CO_2 detector model incorporates an integral CO_2 detector cartridge called $INdCAP^{TM}$ attached to the expiratory port of the resuscitator.

The Nellcor INdGO Manual Resuscitator is single-patient use, non-sterile, latex-free, and available in two sizes: adult and child. It has a double-swivel elbow, three oxygen accumulator styles, and comes in a variety of configurations.

Indications for Use

The Nellcor INdGO Manual Resuscitator is a portable, nonsterile, single-patient use device intended for use on patients requiring manual ventilatory support. During artificial ventilation, the resuscitator can be operated from ambient air or provide oxygen-enriched air using the oxygen accumulator and connecting the supply tubing to a metered oxygen source. The Nellcor INdGO Manual Resuscitator is available with or without an integrated CO2 detector. The

integrated CO2 detector can be used to assist the verification of tube placement during endotracheal or nasotracheal intubation. The integrated CO2 detector detects approximate ranges of CO2 by color comparison.

The Nellcor INdGO Manual Resuscitator is available in two sizes and is for use on the following patient populations:

- Adult size is for use on adults > 30kg.
- Child size is for use on children 10 – 30 kg.

The Nellcor INdGO Manual Resuscitator is intended for use by qualified healthcare professionals in any environment where pulmonary support resuscitation is indicated, such as hospital, transport, mobile, and home. This device is for prescription use only.

Summary of Technological Characteristics of the Device Compared to the Legally Marketed (Unmodified) Device

The method of operation, technological characteristics, and CO2 detector technology of the Nellcor INdGO Manual Resuscitator remain the same as the above referenced predicate device. The only modifications relate to the elbow, NRV housing, check valve cartridge, and canister in the CO_2 cartridge.

Testing

Performance and testing are consistent with the requirements for this device type specified by ASTM F920 and ISO 8382.

Conclusions

The design modifications and results of testing do not raise new questions of safety or effectiveness when compared to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 07 2003

Ms. Gina To
Nellcor Puritan Bennett, Incorporated
4280 Hacienda Drive
Pleasanton, California 94588

Re: K023494
Trade/Device Name: Nellcor® INdGO™ Manual Resuscitator
Regulation Number: 21 CFR 868.5915
Regulation Name: Manual Emergency Resuscitator
Regulatory Class: II
Product Code: BTM
Dated: January 15, 2003
Received: January 16, 2003

Dear Ms. To:

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): K023494

Device Name: Nellcor INdGO Manual Resuscitator

Indications For Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K023494

(Optional Format 3-10-98)

Prescription Use ✓
(Per 21 CFR 801.109)