

DEC 7 1998

Nellcor Puritan Bennett UniProbe Adapter Cable
510(k) Summary *K982728*
December 3, 1998
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1. COMPANY INFORMATION

Establishment: Nellcor Puritan Bennett Inc.
 4280 Hacienda Drive
 Pleasanton, CA 94588

Official Correspondent: Sheryll A. Mathews
 Sr. Regulatory Affairs Specialist

2. DEVICE NAME

Proprietary: UniProbe Adapter Cable

Common/Usual: Adapter Cable

Classification: Oximeter, 74DQA

3. EQUIVALENT DEVICE

The UniProbe/Nellcor brand sensor combination used in conjunction with the specified Ohmeda or Ohmeda-compatible Marquette Tram monitors is substantially equivalent to the specified monitors used in conjunction with an Ohmeda sensor. The 510(k) numbers for the specified monitors/Ohmeda sensor combination are listed below:

| Product | 510(k) Number | Date Cleared |
|---------------------------------------|---------------|--------------|
| Ohmeda Biox 3700/3700e Pulse Oximeter | K850494 | 3/28/85 |
| Ohmeda Biox 3740 Pulse Oximeter | K872772 | 10/7/87 |
| Ohmeda Biox 3760 Pulse Oximeter | K874104 | 12/3/87 |
| Ohmeda 3800 Pulse Oximeter | K962127 | 10/10/96 |
| Marquette Tram Modules | K921669 | 5/7/93 |

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4. DEVICE DESCRIPTION

The UniProbe Adapter Cable allows specified Nellcor brand reusable and patient-dedicated oxygen sensors to be used with specified Ohmeda and Ohmeda-compatible Marquette Tram pulse oximetry monitors, to provide noninvasive measurement of arterial oxygen saturation and pulse rate.

That is, the UniProbe Adapter Cable allows the user to substitute Nellcor brand sensors for Ohmeda brand sensors when measuring SpO₂ with the specified Ohmeda and Ohmeda-compatible Marquette Tram pulse oximetry monitors.

The UniProbe has been designed and tested to be compatible with the following monitors:

Ohmeda Models: 3700, 3700e, 3740, 3760, 3800

Marquette Tram® Models (Ohmeda compatible): 200, 200A, 200SL, 400A, 400SL, 600, 600A, 600SL, 800A, 800SL

The major components of the UniProbe are a molded plastic housing that contains a pair of printed circuit boards sandwiched together. The circuit consists primarily of analog components with no software driven circuitry. The UniProbe's body is approximately 6 inches long with a 10 foot sensor cable attached at one end and a power cable and monitor cable attached at the other end.

The **sensor cable** is approximately ten feet long and terminates in a 9-pin sensor connector that accepts a Nellcor brand oximetry sensor.

The **power cable** and **monitor cable** emerge together from the opposite end of the housing and are approximately eighteen inches long.

The **power cable** terminates in a coaxial barrel connector (power plug) that connects to one of three possible power connectors, depending on the model of monitor it is used with.

The **monitor cable** has a Hypertronics connector (monitor connector) that plugs into the sensor (Patient or SpO₂) port of the oximeter.

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The UniProbe is supplied in 3 different configurations depending on the Ohmeda or Ohmeda-compatible Marquette Tram monitor used. Power must be supplied to the UniProbe using one of three different power connectors as listed in the following table:

| Compatible Monitor | UniProbe Configuration Model Number | Power Connector |
|--------------------------|-------------------------------------|-------------------|
| Marquette Tram Monitors | UP12A | Front Panel Power |
| Ohmeda 3740, 3760 | UP12B | Rear Panel Power |
| Ohmeda 3700, 3700e, 3800 | UP12C | AC Wall Power |

The **Front Panel Power Connector (part of configuration UP12A)** is designed to plug into the "DISPL" socket on the front panel of the Marquette Tram. The UniProbe's power plug plugs into a mating connector mounted within the Front Panel Power Connector.

The **Rear Panel Power Connector (part of configuration UP12B)** connects between the oximeter's own power cord and rear panel power inlet. The UniProbe's power plug plugs into a mating connector mounted within the Rear Panel Power Connector.

The **AC Wall Power Connector (part of configuration UP12C)** consists of a switching power supply that connects to the power plug of the UniProbe.

A UniProbe Adapter Cable is shipped with one power connector, Velcro strips and a DFU in a carton.

5. INTENDED USE

The UniProbe Adapter Cable allows specified Nellcor brand reusable and patient-dedicated oxygen sensors to be used with specified Ohmeda and Ohmeda-compatible Marquette Tram pulse oximetry monitors, to provide noninvasive measurement of oxygen saturation and pulse rate.

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The intended patient population for the UniProbe includes adult, pediatric and neonatal patients. Use with any particular patient requires selection of an appropriate Nellcor brand oxygen sensor.

The UniProbe may be used in any hospital or hospital-type environment where the specified compatible monitors may be used. The UniProbe is contraindicated for use during MRI scanning. The UniProbe is NOT intended for use in the home care environment. The UniProbe is a prescription device and is to be used by qualified health care professionals only.

6. TECHNOLOGICAL CHARACTERISTICS

The new device (a UniProbe/Nellcor brand sensor used with an Ohmeda or Ohmeda-compatible Marquette Tram monitor) and the predicate devices (Ohmeda 3700, 3700e, 3740, 3760, 3800 pulse oximeters and Ohmeda-compatible Marquette Tram monitors all used with an OxyTip sensor), all measure oxygen saturation and pulse rate using equivalent technology. The technological characteristics of the new device and the currently marketed predicate devices are equivalent.

Comparative Performance Evaluations:

The safety and effectiveness of the UniProbe Adapter Cable has been demonstrated by design and testing. Environmental and EMC testing has been conducted as recommended by the applicable sections of the *Reviewer's Guidance for Premarket Notification Submissions*, November 1993. Testing results demonstrated that all applicable requirements have been met.

The accuracy and performance of the Ohmeda or Ohmeda-compatible Marquette Tram monitor/UniProbe/Nellcor brand sensor combinations have been demonstrated through *in vitro* and *in vivo* clinical testing. The Ohmeda 3740/OxyTip A/P combination was compared to the Ohmeda 3700, 3740, 3760, 3800, Tram 600/UniProbe/D25 combination. Test results confirmed that the oxygen saturation accuracy performance of the UniProbe/D25 combination was equivalent to the OxyTip A/P across the recommended device line.

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To further demonstrate that the UniProbe met the stated accuracy specifications, a Co-oximeter Correlation Study (blood study over the specified saturation range of 70% - 100%) was performed using the Marquette TRAM with UP12A, Ohmeda 3740 with UP12B and Ohmeda 3740 with UP12C. These systems are considered representative of all specified Ohmeda and Ohmeda compatible Marquette monitors when used with the appropriate UniProbe Adapter Cable.

The results of the Co-oximeter Correlation Study clearly demonstrate that the UniProbe, when used with the specified Ohmeda or Ohmeda compatible Marquette monitors, meets the stated accuracy specifications.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Sherry Mathews
Nellcor Puritan Bennett Inc.
4280 Hacienda Drive
Pleasanton, CA 94588-2719

Re: K982728
UniProbe Adapter Cable Models UP12A, UP12B and UP12C
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: Undated
Received: November 20, 1998

Dear Ms. Mathews:

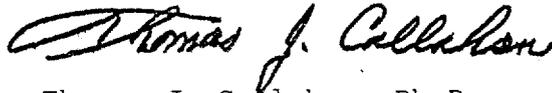
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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 (Pre-market 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

510(k) Number (if known): To be assigned K 982728

Device Name: Nellcor Puritan Bennett UniProbe Adapter Cable

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)

Prescription Use
 (Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

Mark Kramer

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K 982728