K963903

"510(k) Summary"

I. General Information

JAN 27 1998

A. Proprietary Name
Biospectrometer - NB Oximeter Model 1111

B. Common Name
Oximeter

C. Manufacturer & Official Contact Person
The manufacturer of the Biospectrometer - NB Oximeter Model 1111 is:

Hutchinson Technology, Inc. (hereinafter called HTI)
Medical Device Division
40 West Highland Park
Hutchinson, MN 55350-9785
(320) 587-3797 phone
(320) 587-1555 facsimile

The Official Contact Person/Regulatory Consultant is:

Stephan Norsted, PhD., Vice President
Regulatory Strategies, Inc.
7089 Crowne Oak Road
Eden Prairie, Mn 55344
(612) 944-3142 phone
(612) 944-3084 facsimile

D. Regulatory Class and Associated Regulation
per 21 CFR§870.2700 oximeters are Class II (Tier 2) devices under the authority of the Cardiovascular Panel (i.e., MUD).

E. Performance Standards & Special Controls

The Food & Drug Administration has not developed a performance standard for oximeters. Furthermore, oximeters have not been assigned any special controls (e.g., device tracking or postmarket surveillance).

II. Description

The Biospectrometer - NB Oximeter Model 1111 is a spectrophotometric monitoring system which measures an approximated value of percent hemoglobin oxygen saturation in tissue (S_tO_2). More specifically, the Biospectrometer - NB Oximeter measures the percent hemoglobin oxygen saturation of blood contained within the volume of tissue illuminated by the noninvasive probe. The S_tO_2 value is a function of the relative contribution of arterial, venous, and capillary blood.

III. Indications

The Biospectrometer - NB 1111 is intended to noninvasively and continuously measure hemoglobin oxygen saturation:

- in the ear lobe with the 3mm probe
- in the arm, leg, or shoulder with the 15mm probe. The value of these measurements in disease states has not been demonstrated.

IV. Device Description

A. Introduction

The system consists of a patient probe (either 3mm or 15mm) containing optical fibers for transmitting light to tissue and receiving reflected light which is returned to a photo-sensitive detector. The nonsterile probe is designed to be placed on intact skin. The second system component is a monitor containing a spectrometer, light assembly, microprocessor, power supply, display monitor and keyboard. The third type of system component includes two (reference) canisters for use in calibration of the system. The Biospectrometer - NB Oximeter Model 1111 is AC operated.

The Biospectrometer - NB Oximeter Model 1111 measures an approximated value of the percent oxygen saturation of hemoglobin based on spectrophotometric measurement principles. Spectrophotometric measurements of hemoglobin have been well described by numerous authors. Today, spectrophotometric oximeters are commonly used clinically. By measuring absorbencies at suitable wavelengths, the ratio of oxygenated hemoglobin to total hemoglobin can be determined.

The depth of tissue measured by the Biospectrometer - NB Oximeter Model 1111 probe is determined by the probe design. The HTI Biospectrometer - NB 15mm probe measures to a maximum depth of 20mm. The 3mm probe measures to a maximum depth of 4mm.

B. Functional Description

The Biospectrometer - NB Oximeter Model 1111 has the following functional capabilities.

- An approximated value of the percent oxygen saturation of hemoglobin in tissue is measured to a maximum depth of 20 mm with the "15mm" probe and 4 mm with the "3mm" probe.

- The approximated value of the percent oxygen saturation of hemoglobin is presented numerically (current reading along with a trend line on a monitor screen.

- The operator can define an alarm setting for the percent oxygen saturation of hemoglobin (a default value of 40% is provided upon power-up).
- Error messages are provided for the following unsatisfactory conditions:
    - o a low signal error message alerts the operator if the signal falls below a factory set level.
    - o a low light output alerts the operator if the light supplied to the probe is below a factory set level, and
    - o an ambient light error message is presented to the operator if the probe is improperly attached to the patient.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 27 1998

Hutchinson Technology, Inc.
c/o Stephan Norsted, Ph.D.
Regulatory Strategies, Inc.
7089 Crowne Oak Road
Eden Prarie, MN 55344

Re: K963903
Biospectrometer - NB Oximeter Model 1111
Regulatory Class: II (two)
Product Code: 74 MUD
Dated: October 27, 1997
Received: October 29, 1997

Dear Ms. Trimm:

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 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/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

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): K963903

Device Name: Biospectrometer - NB Oximeter Model 1111

Indications For Use:

INDICATIONS

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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)