K061619

5. 510(k) Summary

JUL 12 2006

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510(k) Summary

Submitted by: Hutchinson Technology, Inc.
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Contact Person: Thomas A. Dold
Regulatory Affairs Manager
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Summary Date: 9 June, 2006

Proprietary Name: InSpectra StO_2 Tissue Oxygenation Monitor

Common Name: Tissue Oximeter

CFR Reference: 21CFR§870.2700

Class: II

Product Code: 74MUD

Equivalent Marketed Device: InSpectra Tissue Spectrometer System, Model 325 (K053618)

Device Description: The InSpectra StO_2 Tissue Oxygenation Monitor is designed to estimate the percent oxygen saturation of hemoglobin in a volume of tissue (StO_2)
The InSpectra StO_2 is composed of the following components:

Monitor and Optical Cable: The monitor contains an LCD screen, light detection circuitry, a microprocessor, cooling fan, optical cable, back-up battery, and internal software. The optical cable, permanently connected to the monitor, is a fiber optic light integration cable that contains one set of optical fibers to integrate wavelengths of light and transmit light to the tissue, and a second set of optical fibers that receive light from the tissue and return it to a photosensitive detector. Light emitting diodes in the monitor are the light sources. The monitor has an internal lithium ion battery and two external data ports. It is equipped with an adjustable C-clamp for attachment to an IV pole.

The InSpectra StO_2 Sensor. The single-use InSpectra StO_2 Sensor, when connected to the optical cable, conducts the optical signal to the patient and back to the monitor. The sensor shield protects the measurement from ambient light interference, protects the optical fibers, and has an adhesive surface to facilitate attachment of the sensor to the patient for continuous monitoring.

Intended Use:	Hutchinson Technology Incorporated's InSpectra StO_2 Tissue Oxygenation Monitor is intended for use as a non-invasive monitoring system that measures an approximated value of percent hemoglobin oxygen saturation in tissue (StO_2). The InSpectra StO_2 Tissue Oxygenation Monitor is indicated for use in monitoring patients during circulatory or perfusion examinations of skeletal muscle or when there is a suspicion of compromised circulation.
Technological Characteristics:	The InSpectra StO_2 Oxygenation Monitor device has the same basic technological characteristics as the predicate device based on near-infrared technology. The modified device is equivalent in terms of design, functionality, principles of operation, performance specifications and intended use. When compared to the predicate device, the subject device utilizes an integral LCD display, battery backup system and transmits and receives each wavelength of light serially through the probe rather than simultaneously.
Substantial Equivalence Rationale:	Based on design, technological characteristics, intended use and extensive testing, Hutchinson Technology believes that the subject device is substantially equivalent to the predicate device currently marketed under 510(k) K053618.
Test Conclusions:	Hutchinson Technology, Inc. has conducted extensive testing of the InSpectra StO_2 Tissue Oxygenation Monitor to verify adherence to requirements. All test results verify that the device meets or exceeds all predetermined specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2006

Hutchinson Technology
c/o Thomas A. Dold
Regulatory Affairs Manager
40 West Highland Park NE
Hutchinson, MN 55350

Re: K061619
Trade Name: InSpectra StO_2 Tissue Oxygenation Monitor
Regulation Number: 21 CFR 870.2700
Regulation Name: Tissue Saturation Oximeter
Regulatory Class: II (two)
Product Code: MUD
Dated: June 9, 2006
Received: June 9, 2006

Dear Mr. Dold:

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 (240) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K061619

Device Name: **InSpectra StO_2 Tissue Oxygenation Monitor**

Indications for Use:

Hutchinson Technology Incorporated's InSpectra StO_2 Tissue Oxygenation Monitor is intended for use as a non-invasive monitoring system that measures an approximated value of percent hemoglobin oxygen saturation in tissue (StO_2).

The InSpectra StO_2 Tissue Oxygenation Monitor is indicated for use in monitoring patients during circulatory or perfusion examinations of skeletal muscle or when there is a suspicion of compromised circulation.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 807 Subpart C)

(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 Cardiovascular Devices
510(k) Number K061619