K053618

A113

FEB 8 2006

SMDA Summary – Special 510(k) Modified Device

Submitted by:

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Contact Person:

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Hutchinson Technology, Inc.
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Summary Date:

December 23, 2005

Proprietary Name:

InSpectra™ Tissue Spectrometer System, Model 325

Common Name:

Tissue Spectrometer

CFR Reference:

21CFR§870.2700

Class:

II

Product Code:

74 MUD

Equivalent marketed device:

InSpectra™ Tissue Spectrometer System, Model 325, (K042020)

Device Description:

The **InSpectra**™ is designed to estimate the percent oxygen saturation of hemoglobin in a volume of tissue (StO_2). This value is a reflection of localized perfusion of that tissue.

The **InSpectra**™ is composed of the following components.

- Monitor: The "**InSpectra Tissue Spectrometer**" houses the user interface, and associated electronics. It serves as the analytical and display instrument.

- Patient Cable: The "**Optical Integrator**" transmits light to and from the Tissue Spectrometer and the patient;

- Patient Interface: The "**OptoShield™**" interface is a disposable pad that mechanically attaches to the distal end of the Optical Integrator. Its bottom has an adhesive backing for attachment to the patients skin for continuous monitoring. Until ready for use, the adhesive is covered with a liner to allow intermittent measurements.

- Printer: A "**Thermal Printer**" may be used to print out the StO_2 results for time trending and recording purposes.

- Optical Converter: An "**Optolink™**" RS232 Optical Converter - Model 300 is a device that converts the optical output of the Spectrometer to an electrical signal.

- Set-up Accessories: A "**System Check™**" module with both "High" and "Low" "**Single Point References**" are provided to verify proper system operation.

- Inspectra System Software: Software provided on a compact disk for use on a personal computer that displays data from the tissue spectrometer on a computer during a live session or from an encrypted data file.

Intended Use:

Hutchinson Technology Incorporated's InSpectra™ Tissue Spectrometer System, Model 325, 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™ Tissue Spectrometer 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 modified 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 unmodified device, the modified device raises no new technological issues.

Substantial Equivalence Rationale:

Based on design, technological characteristics, intended use, and extensive testing, HTI believes that the modified device is substantially equivalent to the unmodified predicate device currently marketed under 510(k) #042020.

The modified device raises no new issues of safety or effectiveness.

Test Conclusions:

Hutchinson Technology, Inc. has conducted extensive testing of the modified device 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

FEB 8 2006

Hutchinson Technology, Inc.
BioMeasurement Division
c/o Mr. Joseph P. Ortner
Manager, Product Research
40 West Highland Park NE
Hutchinson, MN 55350

Re: K053618
Trade Name: InSpectra™ Tissue Spectrometer System, Model 325
Regulation Number: 21 CFR 870.2700
Regulation Name: Tissue Saturation Oximeter
Regulatory Class: Class II (two)
Product Code: MUD
Dated: December 23, 2005
Received: December 28, 2005

Dear Mr. Ortner:

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K053618

Device Name: InSpectra™ Tissue Spectrometer System, Model 325

Indications for Use:

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The InSpectra™ Tissue Spectrometer 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__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 K053618