Premarket Notification 510(K) Summary

Submitter:

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Contact:

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Date Prepared:

July 19, 2004

Proprietary Name:

InSpectra™ Tissue Spectrometer System, Model 325

Common Name:

Tissue Spectrometer

CFR Reference:

21CFR§870.2700

Class:

II

Product Code:

74 MUD

Predicate Device:

InSpectra™ Tissue Spectrometer System, Model 325 by Hutchinson Technology Inc. (K012759) and (K023938)

Description:

This premarket notification (510(K) Notification) is submitted to obtain marketing clearance for the Hutchinson Technology Inc. BioMeasurement Division "InSpectra™ Tissue Spectrometer System, Model 325" (hereinafter referred to as InSpectra™).

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 the same version of the previously cleared Hutchinson Technology Inc. (HTI) InSpectra™

Tissue Spectrometer System, Model 325, and represents changes to the indications for use statement.

The InSpectra™ is composed of the following components.

InSpectra™ tissue spectrometer system shown is comprised of the following components:

InSpectra™ Tissue Spectrometer: A spectrometer that contains light detection circuitry, a microprocessor, and a display screen.

InSpectra™ Optical Cable: A fiber optic light integration cable that contains one set of optical fibers to integrate wavelengths of light and transmit to the tissue, and a second set of optical fibers that receives light from the tissue and returns it to a photosensitive detector. Light emitting diodes in the optical cable connector are the light source. Optical cable distal tips are available in 12, 15, 20, 25, and 35mm spacing, and are differentiated by color. The 12-25mm cable tips are gray; the 35mm cable tip is blue. The optical cable is supplied with a storage case.

InSpectra™ Calibrator: A disposable module used to normalize the tissue spectrometer and calibrate during startup of the InSpectra tissue spectrometer system. The calibrator is available in two sizes: 12-25mm (labeled in black) and 35mm (labeled in blue).

InSpectra™ Shield: A disposable interface that attaches to the distal tip of the optical cable. The shield protects the measurement from ambient light interference, protects the optical fibers, and has an adhesive surface to attach to the patient for continuous monitoring and a liner to use for intermittent measurements. The shields are available in two sizes to fit the optical cables and are differentiated by color: 12-25mm (gray) and 35mm (blue). The shield is packaged in the calibrator. To ensure accurate StO_2 measurements, use a new InSpectra shield for each patient. Do not reuse.

InSpectra™ System Check: A method to check system measurements.

InSpectra™ OptoLink™ RS232 Optical Converter: A device used to export StO_2, date, and time data from the spectrometer.

InSpectra™ Software: Software, which 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 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.

The InSpectra™ Tissue Spectrometer System is intended to noninvasively and continuously measure hemoglobin oxygen saturation: in the upper extremity, shoulder, or lower extremity.

Technological Characteristics:

The fundamental changes from the predicate device include:

- A reworded indication-for-use statement (note: the fundamental intended use is retained)

Substantial Equivalence Rationale:

Essentially, the device and its predicate are identical with the exception of a reworded indication for use statement (the fundamental intended use remains unchanged). The devices share the intended use of measuring an approximated value of percent oxygen saturation of hemoglobin in a volume of tissue. In addition, they share the same design principles that incorporate a light source, fiber optic cables (which direct the light to and from the target tissue), optical detectors, analysis of specific wavelengths, and a software algorithm that provides the estimate of hemoglobin oxygen saturation.

Changes to the device necessitating this submission include only a change to the indications for use statement. The basic operating principles and measurement algorithm remain the same.

Test Reports:

Published clinical studies are presented showing that StO_2 measurements provide valuable medical information in various disease states.

Conclusion:

Hutchinson Technology Inc. concludes that the InSpectra™ with changes to the indications for use is substantially equivalent the predicate device, InSpectra™ Tissue Spectrometer System, Model 325.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 15 2004

Hutchinson Technologies, Inc.
c/o Mr. Thomas A. Dold
Regulatory Affairs Manager
Biomeasurement Division
40 West Highland Park NE
Hutchinson, MN 55350

Re: K042020
Trade Name: Inspectra™ Tissue Spectrometer System, Model 325
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II (two)
Product Code: MUD
Dated: July 22, 2004
Received: July 27, 2004

Dear Mr. Kuhn:

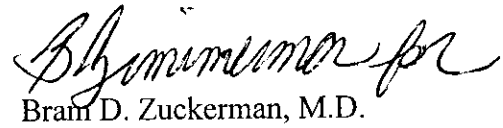
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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) 594-4648. 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,



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

Enclosure

9.0 INDICATIONS FOR USE

Indications For Use Statement

Device Name:

InSpectra Tissue Spectrometer System, Model 325

Indications For Use:

Hutchinson Technology Incorporated's InSpectra™ Tissue Spectrometer System, Model 325, is 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.

The InSpectra™ Tissue Spectrometer System is intended to noninvasively and continuously measure hemoglobin oxygen saturation: in the upper extremity, shoulder, or lower extremity.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___X___ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K042020