K103613

MAR - 2 2011

Hutchinson Technology Incorporated
BioMeasurement Division
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510(k) Summary

1. *Submitter's Name / Contact Person*

Submitted by:
Hutchinson Technology Inc.
BioMeasurement Division
40 West Highland Park Drive NE
Hutchinson, MN 55350

Contact Person:
Colin M. McGraw
Operations Manager
Tel: (320) 587-1272
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Summary Preparation Date: March 2, 2011

2. *General Information*

Trade/Device Name:	**InSpectra**™ StO_2 Spot Check System (Model 300 and accessories)
Common/Usual Name:	Oximeter, Tissue Saturation (StO_2)
Classification Name:	Oximeter, Tissue Saturation
Class:	II
Product Code:	MUD
Classification Panel:	74 (Cardiovascular)
CFR Reference:	21CFR§870.2700

3. *Identification of Substantially Equivalent Device*

K100915: Hutchinson Technology Inc., BioMeasurement Division – InSpectra™ StO_2 Tissue Oxygenation Monitor System (Model 650 and accessories)

4. *Device Description*

The **InSpectra™** StO_2 Spot Check System and its predicate device are designed to estimate the percent oxygen saturation of hemoglobin in a volume of tissue (StO_2). The **InSpectra**™ StO_2 Spot Check System is composed of the following components:

The **InSpectra™** StO_2 Spot Check Monitor (model 300) contains an LCD screen, light source/detection circuitry, microcontrollers, internal software, one set of optical fibers to transmit light to the Cable, a second set of optical fibers that receive light from the Cable and return it to a photosensitive detector and internal software.

The **InSpectra™** StO_2 Cable (model 3003) is a replaceable component of the **InSpectra™** StO_2 Spot Check System that transmits light between the Spot Check and the clip.

The **InSpectra™** StO_2 Thenar Clip (model 1315) has a shield to protect the measurement from ambient light interference and a clip to facilitate the attachment to the patient's thenar for intermittent measurements. The Clip is placed on the thenar eminence (the fleshy mass on the palmar surface the hand at the base of the thumb) and connects to the InSpectra™ StO_2 Cable, model 3003.

The Charging Station contains circuitry to simultaneously charge the **InSpectra™** StO_2 Spot Check Monitor and a spare battery. LED indicators display the status of the charging batteries.

The Spot Check System also includes a replaceable/rechargeable lithium ion battery and a wall/IV pole mounting system

5. ***Intended Use***
Hutchinson Technology Incorporated's **InSpectra™** StO_2 Spot Check is intended for use as a non-invasive monitoring system that measures an approximated value of percent hemoglobin oxygen saturation in thenar skeletal muscle tissue (StO_2).

The **InSpectra™** StO_2 Spot Check is indicated for use in monitoring patients during circulatory or perfusion examinations or when there is a suspicion of compromised circulation of thenar skeletal muscle.

6. ***Technological Characteristics***
The **InSpectra™** StO_2 Spot Check System 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, operating principle, performance specifications and intended use. When compared to the predicate device, the subject device utilizes a multiple-use thenar clip rather than single-use adhesive patient interface. Differences did not affect safety and/or effectiveness.

7. ***Substantial Equivalence Rationale***
The subject device and the predicate device have substantially equivalent indications, intended use, technological characteristics, and performance data. Hutchinson Technology Inc believes that the **InSpectra™** StO_2 Spot Check System is substantially equivalent to the predicate device cleared under 510(k) number: K100915.

8. ***Test Conclusions***
Hutchinson Technology Inc. has conducted extensive testing of the **InSpectra™** StO_2 Spot Check System 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
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Hutchinson Technology, Inc.
% BioMeasurement Division
Mr. Colin M. McGraw
Operations Manager
40 West Highland Park Drive, NE
Hutchinson, Minnesota 55350

MAR - 2 2011

Re: K103613
Trade/Device Name: InSpectra™ StO_2 Spot Check System (Model 300 and accessories)
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: MUD
Dated: February 16, 2011
Received: February 17, 2011

Dear Mr. McGraw:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Bram D.C.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K103613

Device Name: **InSpectra**^{TM} StO_2 Spot Check System (Model 300 and accessories)

Indications For Use:

Hutchinson Technology Incorporated's **InSpectra**^{TM} StO_2 Spot Check is intended for use as a non-invasive monitoring system that measures an approximated value of percent hemoglobin oxygen saturation in thenar skeletal muscle tissue (StO_2).

The **InSpectra**^{TM} StO_2 Spot Check is indicated for use in monitoring patients during circulatory or perfusion examinations or when there is a suspicion of compromised circulation of thenar skeletal muscle.

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K103613