2. 510(k) Summary

Submitter: Redsense Medical AB
Rörkullsvägen 4
Box 287
301 07 HALMSTAD
SWEDEN

MAY 10 2010

Contact Information: Constance G. Bundy
435 Rice Creek Terrace
Fridley, MN 55432
763-574-1976

Submission Date: May 18, 2010

Device Name and Classification: Redsense –Home Use, Class II, 876.5820, 876.5540, product code not known

Submission Purpose: Expand Intended Use to Home Use. The device is equivalent to the Redsense device previously cleared.

Equivalent Device Identification:

Redsense Medical AB K071013

Device Description: Redsense Home Use is a system for monitoring the vein or arterial needle during hemodialysis. Redsense consists of an alarm unit and optical sensor incorporated into an adhesive patch. The patch with the sensor is placed around the vein needle and detects any blood that drips onto the patch if the needle has been accidentally pulled out or if there is leakage during dialysis. If blood loss is detected, the device will alarm.

Intended Use/Indications for Use:
The Redsense device is intended to monitor for potential blood loss from the hemodialysis access site in hemodialysis patients undergoing hemodialysis treatment up to 5 hours at home or in the clinical setting. The device includes a blood sensor incorporated into an adhesive dressing. The sensor monitors potential blood leakage from the needle puncture via an infrared light and will alarm if needle dislodgement or blood leakage is detected.
All use must be administrated under physician's prescription, and must be observed by a trained and qualified person considered to be competent in the use of this device by the prescribing physician.

Summary of Testing:
Verification testing including additional tests of the audible and visual capability of the alarm has been performed to verify that the Redsense Home Use device fulfills the Requirement Specifications and additional FDA requirements. The audible testing of the alarm was conducted according to the requirements stated in "Class II Special Controls Guidance Document: Apnea

Monitors". This Guidance document specifies a sound level of 75 dB (A) and the test resulted in a sound level of 76 dB(A) measured at 10 feet. The sound test was also conducted to verify the sound level at different temperatures specified within the temperature range of the product's usage.

Another additional test was performed to evaluate the visibility of the LEDs in different background light levels as stated in the standard referred to in the "Class II Special Controls Guidance Document: Apnea Monitors", that is ISO 9703-1:1992: "Alarm signals for anesthesia and respiratory care. Part 1. Specification for visual alarm signals" The results met the requirements in the standard.

User Evaluation was conducted by eight patients. The evaluation was performed on 8 patients undergoing self dialysis at clinic or dialysis at home in Sweden. The objective of the evaluation was to evaluate if Redsense could be used by the patients and to evaluate if the Instructions for use were sufficient.The evaluation showed that the amount of false alarms and warnings did not increase compared to the device as used in the clinical settings. The evaluation showed no adverse effects. Even if the evaluations showed that the device can be handled by the patient themselves, the intended use for the product requires that all use of the device in the home "must be observed by a trained and qualified person considered to be competent in the use of this device by the prescribing physician". Results showed the device functioned successfully in the home use environment.

Conclusion: Redsense Home Use device is equivalent to the Redsense device previously cleared with the addition of the home use indication. A minor difference includes an increase in the sound level. This was accomplished by minor changes regarding placement of components on the PC board inside the alarm unit. Verification and user evaluation show the Redsense Home Use device to be safe and effective for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G6(
Silver Spring, MD 20993-0002

MAY 10 2010

Redsense Medical AB
c/o Ms. Constance G. Bundy
C. G. Bundy Associates, Inc.
435 Rice Creek Terrace
FRIDLEY MN 55432

Re: K092955
Trade/Device Name: Redsense – Home Use
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device
Regulatory Class: II
Product Code: ODX
Dated: May 4, 2010
Received: May 7, 2010

Dear Ms. Bundy:

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,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Redsense Medical AB
Halmstad, Sweden

1. Indications for Use

510(k) Number (if known): K092955

Device Name: Redsense – Home Use

Indications for Use:

The Redsense device is intended to monitor for potential blood loss from the hemodialysis access site in hemodialysis patients undergoing hemodialysis treatment up to 5 hours at home or in the clinical setting. The device includes a blood sensor incorporated into an adhesive dressing. The sensor monitors potential blood leakage from the needle puncture via an infrared light and will alarm if needle dislodgement or blood leakage is detected.
All use must be administrated under physician's prescription, and must be observed by a trained and qualified person considered to be competent in the use of this device by the prescribing physician.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
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