FEB 10 2011

510(k) Summary

Submitter: Redsense Medical AB
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Contact Information: Constance G. Bundy
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Submission Date: October 26, 2010, Revised January 31, 2011

Device Name and Classification: Redsense –Alarm unit and sensor for Clinical Use (Model RA-1-RA001C), Class II, 876.5820, 876.5540, product code ODX

Submission Purpose: Expand Intended Use for up to 8 hours clinical use.

Equivalent Device Identification:

Redsense Medical AB K071013
Redsense Medical AB K092955
Gambro, Inc K070643

Device Description: Redsense is a system for monitoring the vein needle during hemodialysis. Redsense consists of an alarm unit and optical sensor incorporated into an adhesive patch. The patch with the sensor is placed over 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: The Redsense device is intended to monitor for potential blood loss from a hemodialysis access site in patients undergoing continuous hemodialysis treatment up to 8 hours in the clinical setting. The device includes a blood sensor incorporated into an adhesive sensor patch. The sensor monitors potential blood leakage from the venous needle puncture site via an infrared light and will alarm if blood leakage is detected via absorption onto the device's sensor patch.

Comparison Table:

Parameter	Proposed Device	Predicate device 1	Predicate 2	Predicate Device 3
Device	Redsense Alarm Unit, Clinical Use, RA-1-RA001C	Redsense Alarm Unit	Redsense Alarm Unit. Home use	Phoenix HEMODIALYSIS DELIVERY SYSTEM
For use at:	Clinic	Clinic	Home or clinic	Clinic
Intended Use	The Redsense device is intended to monitor for potential blood loss from the hemodialysis access site in hemodialysis patients undergoing continuous hemodialysis treatment up to 8 hours in the clinical settings. The device includes a blood sensor incorporated into an adhesive sensor patch. The sensor monitors potential blood leakage from the venous needle puncture site via an infrared light and will alarm if blood leakage is detected via absorption onto the device's sensor patch.	The Redsense device is intended to monitor for potential blood loss from the hemodialysis access site in hemodialysis patients undergoing continuous hemodialysis treatment up to 5 hours in the clinical setting. The device includes a blood sensor incorporated into an adhesive sensor patch. The sensor monitors potential blood leakage from the venous needle puncture site via an infrared light and will alarm if blood leakage is detected via absorption onto the device's sensor patch.	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.	The Phoenix Hemodialysis delivery system is intended to be used to provide high flux and low flux hemodialysis, hemofiltration and ultrafiltration on patients weighing 15 Kilograms or more. The Phoenix system is to be used with either high or low permeability dialyzers. The device is intended to be used by trained operators when prescribed by a physician, in a chronic care dialysis facility or acute care unit.
Maximum Dialysis Time	8 hours	5 hours	5 hours	8 hours

Summary of Testing: Verification testing has been performed to verify that the Redsense device fulfills the Requirement Specifications and can be used for up to 8 hours in a clinical setting. Additional tests of the audible and visual capability of the alarm have been performed. Test results met the requirements of the standards used for testing.

Conclusion:

Redsense device is identical to the Redsense device previously cleared with the addition of the 8 hour clinical use indication. Verification testing showed the Redsense device to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

FEB 10 2011

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

Re: K103242
Trade/Device Name: Redsense Alarm Unit for Clinical Use, Model RA-1-RA001C
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: ODX
Dated: February 3, 2011
Received: February 8, 2011

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,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103242

Device Name: Redsense Alarm Unit for Clinical Use, Model RA-1-RA001C

Indications For Use:

The Redsense device is intended to monitor for potential blood loss from the hemodialysis access site in hemodialysis patients undergoing continuous hemodialysis treatment up to 8 hours in the clinical settings. The device includes a blood sensor incorporated into an adhesive sensor patch. The sensor monitors potential blood leakage from the venous needle puncture site via an infrared light and will alarm if blood leakage is detected via absorption onto the device's sensor patch.

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

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K103242