clearcount MEDICAL SOLUTIONS

K093557

DEC 18 2009

5. 510(K) SUMMARY (21 CFR 807.92) CLEARCOUNT MEDICAL SmartWand-DTX® SYSTEM

510(k) Owner: ClearCount Medical Solutions, Inc.
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Date Prepared: September, 2009

Trade Name: SmartWand-DTX™ System

Common Name: Surgical sponge counter

Classification Name: Surgical sponge counter, unclassified, 21 CFR 888.2740, LWH

Predicate Devices: ClearCount Medical SmartSponge® Plus System K073180
RF Surgical Systems Detection System K062642

Device Description: The SmartWand-DTX™ System is based on radio frequency identification (RFID) tags. The RFID tags are provided to manufacturers of surgical disposables for inclusion into their surgical sponges, laparotomy pads and surgical towels. The disposable manufacturer permanently attaches the RFID tags to the gauze or fabric of the disposables. The tags are then programmed to contain information about the type and number of disposables in the package. This allows the sponges, pads, and towels to be individually recognized by an RFID reader. The RFID tag function is the same as that for the SmartSponge Plus System.

The SmartWand-DTX is a device comprised of a handheld scanning antenna that is attached to an electronics box that contains an RFID reader and supporting electronics. Integrated RFID technology allows the capture of the information coded on the unique RFID tags in the sponges, pads and towels. When the tagged sponges, pads, and towels are detected by the scanning wand, the device displays the type and number of each type of item that is detected. The system recognizes RFID-tagged items that may be inside the surgical site.

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A SmartTag is a disposable RFID tag that is approximately the size of a business card. Like the RFID-tagged sponges, the SmartTags contain unique identifying numbers and are distinguishable by the system software. The SmartTag is placed on the operating room table before the patient is brought into the room and is covered by the standard sheets or drapes used in surgery, thus not making contact with the patient. The SmartTag provides feedback to the user that the detection wand is being held close enough to the patient to ensure proper scanning.

Intended Use:

The ClearCount Medical Solutions SmartWand-DTX System is indicated for use in counting and displaying the number of RFID-tagged surgical sponges, laparatomy sponges, and towels detected by the device and providing a non-invasive means of locating retained RFID-tagged surgical sponges, towels, and other tagged items within a surgical site.

The indications are a subset of those of the ClearCount SmartSponge® Plus predicate device in that it provides a non-invasive means of identifying retained RFID-tagged surgical sponges, towels, and other tagged items within a surgical site. This indication is also consistent with the RF Surgical Systems Detection System.

The ClearCount Medical Solutions SmartWand-DTX System, like the SmartSponge Plus System, relies on permanently affixed radiofrequency identification (RFID) tags to convey unique identification information about each item, unlike the RF Surgical Detection System which uses resonant frequency tags which creates a field disturbance that may indicate the presence of an item.

The addition of unique identifying information allows the SmartWand-DTX to identify specific attributes, such as the type and quantity of sponges, in an identical manner to the ClearCount SmartSponge Plus predicate device. The ability to distinguish tags uniquely also enables the operation of the SmartTag for aiding in the effective scanning of the surgical site.

Technological Characteristics:

The RFID tags attached to surgical disposables identifies each item to the SmartWand-DTX which reads the tag information with an RFID reader controlled by proprietary software operating on a microcontroller unit. The wand can read the tag through a human body. The device software uses the scanned information to display the type and number of each type of item detected during a scan.

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The ClearCount SmartWand-DTX System, like the SmartSponge Plus predicate, has a tethered detection wand that uses the same power and control system and same display as the SmartSponge Plus detection wand. The detection wand is used in a similar manner to the RF Surgical Detection System. However, the ClearCount detection wand is provided as a permanent device rather than a single-use disposable. A disposable sterile sheath will be provided for covering the detection wand and the portion of the wand cable that may contact the sterile field.

The SmartWand-DTX System, like the SmartSponge Plus System predicate device, uses RFID technology to communicate unique identification data from tagged items to the reader. This technology is also similar to that of the RF Surgical Detection System predicate, (K062642). Both systems rely on passive tags, which hold no electric charge and remain inactive until energized by a reader in close proximity. RF Surgical tags resonate when excited by a specific radio frequency, causing a specific frequency response which is detected by the RF Surgical Detection Wand. The presence of a resonant tag then alerts the system that a tagged item is within the specified range of the RF Surgical Wand. The ClearCount System also uses a specific radio frequency which causes its passive tags to resonate when within the range of the ClearCount Wand. In the ClearCount System, these tags contain unique identifying information which is stored and used by the device to detect the presence of a tagged item as well as provide descriptive information about the detected items.

The system has also been designed to meet the following electrical safety standards and electromagnetic compatibility standards:

UL 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety

IEC 60601-1-2 (Edition 2.1 – 2004-11) Medical Electrical Equipment - Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility - Requirements and Tests

Non-Clinical Performance Data:

Non-Clinical testing included simulated use of the device in a laboratory setting. The SmartWand-DTX uses the same RFID technology and hardware as the SmartSponge Plus. The performance of the SmartWand-DTX is actually enhanced over the SmartSponge Plus scanning wand in that the wand is pre-tuned

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thereby making the software algorithm less complex such that the scanning speed is increased. The SmartWand-DTX System performed as intended in the verification and validation testing. Biocompatibility of the transponder tag was illustrated and is comparable to the commercially available predicates. The validated software functioned as intended under simulated use, properly locating all tags. This testing supports a determination of substantial equivalence to products and technologies previously cleared by FDA.

Conclusions: The data and information demonstrates that the ClearCount SmartWand-DTX™ System provides an added measure of safety and effectiveness to the current methods of gauze and sponge detection presently used in the surgical environments.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

ClearCount Medical Solutions, Inc.
% Regulatory Technology Services, LLC
Mr. Mark Job
1394 25th Street, Northwest
Buffalo, Minnesota 55313

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Re: K093557
Trade/Device Name: ClearCount Medical Solutions SmartWand-DTX™
Regulation Number: 21 CFR 880.2740
Regulation Name: Surgical sponge scale
Regulatory Class: Class I
Product Code: LWH
Dated: December 3, 2009
Received: December 4, 2009

Dear Mr. Job:

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 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/cdrh/mdr/ 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/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): New Submission K093557

Device Name: ClearCount Medical Solutions SmartWand-DTX™

Indications For Use: The ClearCount Medical Solutions SmartWand-DTX™ System is indicated for use in counting and displaying the number of RFID-tagged surgical sponges, laparatomy sponge, and towels detected by the device and providing a non-invasive means of locating retained RFID-tagged surgical sponges, towels, and other tagged items within a surgical site.

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 IFNEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon for mkm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093557