

**5. 510(K) SUMMARY (21 CFR 807.92)**  
**CLEARCOUNT MEDICAL SMARTSPONGE™ SYSTEM**

510(k) Owner: ClearCount Medical Solutions, Inc.  
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NOV 19 2007

Date Prepared: August, 2007

Trade Name: SmartSponge™ PLUS System

Common Name: Surgical sponge counter

Classification Name: Surgical sponge counter, <sup>class 1</sup> ~~unclassified~~, 21 CFR <sup>890</sup> ~~888~~.2740, LWH

Predicate Devices: ClearCount Medical SmartSponge System K071355  
RF Surgical Systems Detection System K062642  
Dukal Corp. X-ray detectable sponges (Various) 510(k) Exempt

Device Description: The SmartSponge™ PLUS System includes surgical sponges, laparotomy pads and surgical towels, each of which contains a unique radio frequency identification (RFID) tag permanently attached to the gauze or fabric. The tags allow the sponges and towels to be individually recognized by an RFID reader.

The SmartBucket is a specially designed cart containing a microcontroller unit with specialized software designed for mobile data collection. Integrated RFID technology allows capture of the information coded on the unique RFID tag on the sponges, pads and towels. The microcontroller unit counts the initial number of sponges introduced into a surgical case, and using the custom software program, reports the total sponges discarded at the end of the procedure, and compares that number to the original. By providing a count of the items entered into surgery, and a count of those discarded and removed permanently from the surgical field, personnel can be alerted to sponges that may still remain in the surgical field prior to closing the patient.

A Detection Wand is an additional antenna that is tethered by a cable to the SmartBucket. It is powered and controlled by the SmartBucket. The antenna functions as an additional RFID antenna to the system, functioning in an identical manner to the internal SmartBucket antennas. By using a keypad the user may select activate the Detection Wand antenna. When in Detection Wand mode, the system uses the Wand antenna to recognize RFID-tagged items that may be inside the surgical site.

A Detection Mat is a disposable or reusable element with multiple RFID tags embedded inside, along with several passive printed circuit traces. Like the RFID-tagged sponges, the Detection Mat tags contain unique identifying numbers and are distinguishable by the system software. The Detection Mat 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 RFID tags in the Mat provide feedback to the user that the Detection Wand is being held close enough to the patient to ensure proper reading. The tags in the Detection Mat also ensure that the Detection Wand scan has covered the appropriate areas of the patient. The passive circuit traces help to enhance the readability of the RFID tags in the Detection Mat.

Intended Use:

The ClearCount Medical Solutions SmartSponge™ PLUS System is indicated for use in counting and recording the number of RFID-tagged surgical sponges, laparotomy sponges and towels used during surgical procedures, as well as for providing a non-invasive means of locating retained RFID-tagged surgical sponges, towels, and other tagged items within a surgical site.

The indications expand upon those of the ClearCount SmartSponge™ predicate device by the addition of providing a non-invasive means of locating retained RFID-tagged surgical sponges, towels, and other tagged items within a surgical site. This additional indication is identical to that of the RF Surgical Systems Detection System.

The ClearCount Medical SmartSponge™ PLUS System, like the original SmartSponge™ 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 identify only the presence of an item. The detection of items in each system is otherwise comparable.

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

ClearCount SmartSponge™ surgical sponges have indications for use similar (with the exception of RFID detection) to those of their predicates, X-ray detectable sponges.

Technological  
Characteristics:

Surgical sponges from ClearCount Medical Solutions are identical to those of Dukal Corporation in terms of technological characteristics. Both are non-absorbable gauze with x-ray detectable strips. The ClearCount Medical Solutions sponges, pads and towels have a unique radiofrequency identification tag securely sewn into every sponge, pad and towel. The tag identifies the product to the SmartBucket cart which reads the label with a commercially available RFID reader controlled by specialized software operating on a microcontroller unit. The scanner can read the tag through blood and other bodily fluids and tissue. A customized software program uses the scanned information to count the number of items used at the beginning of a surgical procedure, and then again before surgical closure. The sponge count in and out of the procedure can be helpful in determining if any sponges may still be inside a patient. Procedural sponge counts can be obtained on demand from the mobile computer, or at the end of the procedure for a final report.

The ClearCount SmartSponge™ PLUS System, like the SmartSponge™ predicate, relies on multiple RFID antennas inside the device to read tagged items. An additional antenna is provided as a tethered Detection Wand, using the same power and control system and same display as the SmartBucket. The Detection Wand is used in a similar manner to the RF Surgical Detection System. The ClearCount Wand is provided as a permanent device rather than a single-use disposable. A sterile sheath will be provided for covering the Detection Wand and the portion of the Wand cable that may contact the sterile field with each use.

The SmartSponge™ PLUS System, like the SmartSponge™ System predicate device, uses RFID technology to communicate unique identification data from tagged items to the reader. This technology is 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 to identify the presence of a tagged item as well as descriptive information about the detected items.

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

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

IEC 60601-1-2 (Second Edition, 2001) Medical Electrical  
Equipment - Part 1: General Requirements for Safety;  
Electromagnetic Compatibility - Requirements and Tests

Non-Clinical

Performance Data: Non-Clinical testing included simulated use in patient models that represented worst case biological situations as well as manufacturing process situations and in all cases the ClearCount SmartSponge™ PLUS System performed as intended. 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 SmartSponge™ PLUS System provides an added measure of safety and effectiveness to the current methods of gauze and sponge counting presently used in the surgical and clinical environments.



Food and Drug Administration  
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NOV 19 2007

Clearcount Medical Solutions, Inc.  
% Regulatory Technology Services, LLC  
Mr. Mark Job  
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Re: K073180

Trade/Device Name: ClearCount Medical Solutions SmartSponge™ PLUS System  
Regulation Number: 21 CFR 880.2740  
Regulation Name: Surgical sponge scale  
Regulatory Class: I  
Product Code: LWH  
Dated: November 12, 2007  
Received: November 13, 2007

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 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.

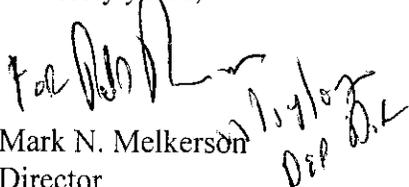
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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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 (240) 276-0115 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

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

Enclosure

