clearcount
MEDICAL SOLUTIONS

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

510(k) Owner: ClearCount Medical Solutions, Inc.
700 River Avenue, Suite 100
Pittsburgh, PA 15212
Tel: 412-322-4110
Fax: 412-291-1091

Contact Person: Steven Fleck
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E-mail: steve@clearcount.com

Date Prepared: October, 2006

Trade Name: SmartSponge™ System

Common Name: Surgical sponge and surgical sponge counter

Classification Name: Nonabsorbable gauze for internal use per 21 CFR 878.4450, GDY
Surgical sponge counter, unclassified, 21 CFR 880.2740, LWH

Predicate Devices: Dukal Corporation X-ray detectable surgical sponges
SurgiCount Medical, Inc. Safety-Sponge System, K060076
Digital Angel Corporation VeriChip implantable radio frequency transponder system, K033440

Device Description: The SmartSponge™ System includes surgical sponges, laparatomy pads and surgical towels, each unit 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.

Intended Use:

The ClearCount Medical Solutions SmartSponge™ System is indicated for use in counting and recording the number of RFID-tagged surgical sponges, laparatomy sponges and towels used during surgical procedures.

The indications are similar to those of the predicate device, the SurgiCount Medical Safety-Sponge System; "for use in counting and recording the number thermally labelled surgical sponges, laparatomy sponges and towels used during surgical procedures." The ClearCount Medical SmartSponge™ System relies on permanently affixed radiofrequency identification tags rather than thermal labels to convey unique identification information about each item. The counting of items in each system is otherwise comparable, and the mode of communication is not critical to the intended use of the device and its software.

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 bodily fluids. A customized software program, similar to the predicate software for the SurgiCount Medical Safety-Sponge System, 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 SmartSponge™ System uses RFID technology to communicate unique identification data from tagged items to the reader. This technology is similar to that used in the Digital Angel Corporation's VeriChip implantable radio frequency transponder system, (K033440). Both systems rely on passive RFID tags, which hold no electric charge and remain inactive until energized by an RFID reader in close proximity. Digital Angel's VeriChip transponders store and communicate a unique identification number which may be used to access a database containing the

patient's identity and health information. ClearCount's transponders store and communicate a unique identification number which is used to catalog each item used in a particular surgery.

Non-Clinical Performance Data: Non-clinical testing included demonstrating permanence of the tag on gauze pads, biocompatibility of the tag material, manufacturing validation that one and only one unique tag was placed per item, software validation of the SmartBucket scanning device, and simulated finished product testing of the total system. Results showed that the tags are permanently attached, and that the material is comparable to commercially available predicates in terms of biocompatibility. The validated software functioned as intended under simulated use, properly counting sponges in simulated body fluids. The testing supports a determination of substantial equivalence to products and technologies previously cleared by FDA.

Conclusions: Test results demonstrate the RFID tagged sponges are as safe as the predicate device, and the software installed on the microcontroller unit performs accurately, making its use more effective and more accurate than hand counting sponges.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

ClearCount Medical Solutions, Inc.
% Intertek Testing Services
Mr. Daniel W. Lehtonen
2307 East Aurora Road, Unit B7
Twinsburg, Ohio

MAY 24 2007

Re: K071355
Trade/Device Name: ClearCount Medical Solutions SmartSponge™ System
Regulation Number: 21 CFR 880.2740
Regulation Name: Surgical sponge scale
Regulatory Class: I
Product Code: LWH, GDY
Dated: May 14, 2007
Received: May 15, 2007

Dear Mr. Lehtonen:

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.

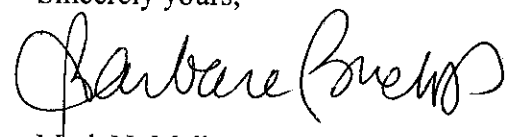
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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.

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

4. INDICATIONS FOR USE STATEMENT

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

Device Name: ClearCount Medical Solutions SmartSponge™ System

Indications For Use: The ClearCount Medical Solutions SmartSponge™ System is indicated for use in counting and recording the number of RFID-tagged surgical sponges, laparotomy sponges, and surgical towels used during surgical procedures.

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)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071355