K060076

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SURGICOUNT MEDICAL
A Division of Patient Safety Technologies, Inc.
You Can Count On Us.™

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MAR 14 2006

510(K) SUMMARY (21 CFR 807.92)

SURGICOUNT MEDICAL SAFETY-SPONGE SYSTEM

510(k) Owner:	SurgiCount Medical division of Patient Safety Technologies, Inc. 27555 Ynez Road, Suite 330 Temecula, CA 92591 Tel: 951-587-6201 Fax: 951-587-6237
Contact Person:	Sharon Rockwell Tel: 714-695-9269 E-mail: srockwell@writeme.com
Date Prepared:	December, 2005
Trade Name:	Safety Sponge™ 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 888.2740, LWH
Predicate Devices:	Tyco/Kendall X-ray detectable surgical sponges Tyco BAG-IT Sponge Counting System SMS Blood Bank Transfusion System, BK960036
Device Description:	The Safety Sponges include surgical sponges, laparatomy pads and surgical towels, each unit of which contains a unique identification label permanently fused to the gauze or fabric. The labels allow the sponges and towels to be individually recognized by a commercially available sight laser imager. The Safety Sponge Counter is a commercially available mobile computer with specialized software designed for mobile data collection. Integrated imaging technology allows capture of the information coded in the unique identification label on the sponges, pads and towels. The computer counts the initial number of sponges opened, and using the custom software program, reports the total sponges used at the end of the procedure or on

demand, and compares that number to the original. Individual sponges may be identified as entered into the surgical field but not discarded, so that the surgical field can be explored before surgically closing the patient.

Intended Use:

The SurgiCount Medical Safety-Sponge System is indicated for use in counting and recording the number of thermally labeled surgical sponges, laparatomy sponges and surgical towels used during surgical procedures.

The indications are similar to those of the predicate device, BAG-IT Sponge Counting System by Tyco; "for efficient counting and containment of lap sponges, and for constant visibility for assessing blood loss and counting of sponges."

The SurgiCount Medical indications are also comparable to a software module from Advanced Medical Systems (AMS), approved under 510(k) BK960036, "for inventory management of blood bank transfusion systems, which require unique identifications." Though the AMS software module is used for blood bags, it is designed to run on general purpose hardware platforms supplied by commercial manufacturers, and records patient identification, counts of blood bags in different stages of inventory, and reports the total number of bags in a particular location, or on demand. The counting of blood bags is comparable to the counting of surgical sponges and is not critical to the intended use of the software.

Technological Characteristics:

Surgical sponges from SurgiCount Medical are identical to those of Tyco/Kendall in terms of technological characteristics. Both are non-absorbable gauze with x-ray detectable strips. The SurgiCount Medical sponges, pads and towels have a unique identifying label thermally attached to every sponge, pad and towel. The thermal label identifies the product to the hand held scanner which reads the label with a commercially available laser imaging reader on a mobile computer. The scanner can read the label through blood and bodily fluids. A customized software program, similar to the predicate software for inventory control of blood bags, uses the scanned information to count the number of items used at the beginning of a surgical procedure, and then again at appropriate times as indicated by hospital practice, such as just 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 permanent report.

Non-Clinical Performance Data: Non-clinical testing included demonstrating permanence of the label on gauze pads, biocompatibility of the label material, manufacturing validation that one and only one unique label was placed per pad, software validation of the hand-held scanning device, and simulated finished product testing of the total system. Results showed that the gauze labels do not flake or peel, 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 and providing hard copy reports equivalent to those used for blood bag inventory products. The testing supports a determination of substantial equivalence to products and technologies previously cleared by FDA.

Clinical Data: The SurgiCount Safety-Sponge System has been tested clinically under non-significant risk IRB approvals in a surgical setting. The device functioned as intended, and accurately counted surgical sponges into and out of the field, on both clean and soiled sponges. The study compared accuracy of sponge counts as well as time spent for counting sponges, and operating personnel's assessment of the software program and ease of use. No adverse events were reported. Results supported substantial equivalence to commercially available surgical sponges and counters used for inventory control of other medical devices.

Conclusions: The non-clinical and clinical test results demonstrate the thermally labeled sponges are as safe as the predicate device, and the software installed on the commercially available mobile computer performs accurately, making its use more effective than hand counting sponges. The system provides improved accuracy, comparable to inventory control systems used for blood bag counting.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 14 2006

SurgiCount Medical
c/o Rockwell & Associates
Ms. Sharon Rockwell
5582 Chalon Road
Yorba Linda, California 92886

Re: K060076
Trade/Device Name: SurgiCount Medical Safety-Sponge System
Regulation Number: 21 CFR 880.2740
Regulation Name: Surgical sponge scale
Regulatory Class: I
Product Code: LWH
Dated: December 21, 2005
Received: January 10, 2006

Dear Ms. Rockwell:

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

TAB 4

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K060076

Device Name: SurgiCount Medical Safety-Sponge System™

Indications for Use:

The SurgiCount Medical Safety-Sponge System™ is indicated for use in counting and recording the number of thermally labeled surgical sponges, laparotomy sponges and towels used during surgical procedure.

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)

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

510(k) Number K060076