Attachment 2 16 Mar 2012 revised section for K120473

5.0 510(k) Summary K120473

Submitters Name and Address
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APR - 9 2012

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Date Prepared
16 Mar 2012

Name of Medical Device
Device Classification Name: Counter, Surgical Sponge
Device Classification Number: 21 CFR 880.2740
Device Class: Class 1
Proprietary Name: Gauss Pixel App

Predicate Device
Bag-It™ Sponge Counter Bags (Tyco/Covidien) (K912824)

Device Description
The Gauss Pixel App is a software program used on an iPad tablet to capture images of sponges to assist surgical personnel in the management of surgical sponges after surgical use. The App allows surgical personnel to categorize sponges by sponge type and provides an automated ongoing count of total sponge images and sponge images by tag. It also provides a visual record of images for further evaluation. This program is not intended to replace existing sponge counting practices and sponges should be retained per the user's standard sponge management practice until the case is complete and sponge counting has been finalized.

Intended Use

The Gauss Pixel App is intended to be used to aid current clinical practices in recording the number of surgical sponges and for visibility for assessment of sponge images.

The App is intended to be used in the Operating Theatre to assist users with sponge management practices by providing another method to visually capture and display images of used sponges using software running on an iPad mobile platform. Running the

software, the user captures images of each sponge prior to storing per their standard sponge management practices. The user may categorize the sponge by type. The user may review each image to re-assign sponge type, confirm image quality or delete the image if appropriate. The software counts the images and displays an ongoing count of total sponges and sponges by sponge type as categorized by the user. The software allows users to re-review each sponge image and a display panel of all used sponges to assist in sponge management and review. The sponge image is captured in a fully expanded state, providing a full view of each sponge prior to storage per current clinical practices.

The indications for use for the predicate and proposed device differ in that the proposed device is intended to 'aid current practices' which means it is intended to be used in conjunction with current practices. The software automates the counting procedure and this counting has been verified through verification and validation testing. This difference does not affect the safety or efficacy of the device as it is labeled as an adjunctive product.

Technology

Both the Pixel App and the predicate device utilize visual assessment of sponges to count the number of surgical sponges used in a surgical procedure. The predicate device uses a plastic bag with partitions to separate each sponge for counting and review purposes while the Pixel App uses software running on an iPad mobile platform for counting and review purposes. The Pixel App and the predicate device are intended to be used together so that either method of visual assessment may be used during the surgical procedure and a final sponge count may be made by the user. This software technology has been verified to provide an accurate count of all images and by image type as categorized by the user and does not introduce new questions of safety as the user is advised to retain all sponges using standard sponge management practices and can re-review sponges physically at the end of the procedure if needed.

Technologic Comparison

Technologic method for:	Predicate	Gauss Pixel App
Sponge management	Sponges are collected and stored in partitions within the plastic bag.	Sponges are collected and stored in partitions within the plastic bag or other sponge management method selected by user.
Sponge counting	User manually counts sponges as seen in partitions and calculates a total.	User captures image of each sponge prior to storing per current sponge management practices and software counts each image, providing an ongoing total on the iPad mobile platform.
Sponge typing	Not available unless user opts to use separate containers for each sponge type.	User assigns sponge type for each image captured.

Technologic method for:	Predicate	Gauss Pixel App
Sponge counting by type	Not available unless user opts to use separate containers for each sponge type and totals each type separately.	Software counts each image by assigned type, providing an ongoing total.
Visual assessment of each sponge	User can view and assess each sponge in a wadded up state in partitions.	User can view and assess each sponge in an open/unfolded state by re-reviewing any selected image.
Visual assessment of all sponges used in a clinical procedure	User can view and assess the entire 'sheet' of sponges (or series of sheets) as stored in the individual partitions.	User can view and assess all sponges in an open/unfolded state in a grid-like display of all sponges captured during a procedure.

Performance

Results of performance testing confirmed that the application provided instructions for use, recorded images as indicated by the user, accurately tagged images as indicated by the user, accurately provided automated counting both in total and by type and allowed visual review and management (re-tagging, deletion) of all images as appropriate. Results of performance testing through the software verification and validation process demonstrate that the Gauss Pixel App functions as intended and is substantially equivalent to the predicate device.

Substantial Equivalence

The Gauss Pixel App is as safe and effective as the predicate. The Gauss Pixel App has the same intended uses and indications and utilizes a new technological method (software) which complements current clinical practices and does not raise new issues of safety or effectiveness. Software verification and validation demonstrate that the Gauss Pixel App functions as intended. Thus, the Gauss Pixel App has been shown to be substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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APR - 9 2012

Re: K120473
Trade/Device Name: Gauss Pixel App
Regulation Number: 21 CFR 880.2740
Regulation Name: Surgical sponge scale
Regulatory Class: I
Product Code: LWH
Dated: March 16, 2012
Received: March 19, 2012

Dear Ms. McLaughlin:

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,

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

Enclosure

Attachment 1 16 Mar 2012 revised section for K120473

4.0 Indications for Use Statement

Indications for Use Form

510(k) Number: K120473

Device Name: Gauss Pixel App

Indications for Use:

The Gauss Pixel App is indicated for use to aid current practices in recording the number of surgical sponges and for visibility for assessment of sponge images.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard P. Rhoads for Mark Ogden
Branch Chief
6/1/12

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120473