K062642
1/3

510(K) SUMMARY (21 CFR 807.92)

RF SURGICAL SYSTEMS INC. DETECTION SYSTEM

510(k) Owner: RF Surgical Systems Inc.
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Bellevue WA 98005
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Contact Person: Martin Sellers
Director of Manufacturing and RA/QA
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NOV - 2 2006

Date Prepared: August 18, 2006

Trade Name: RF Surgical Systems Inc. Detection System

Common: Surgical Sponge Counter

Classification Name: Surgical Sponge Counter, unclassified, 21 CFR 888.2740

Predicate Devices: SurgiCount Medical, Safety Sponge™ K060076
Tyco/Kendall X-ray Detectable Sponges (Various) 510(k) Exempt
Tyco Bag-IT Sponge Counting System 510(k) Exempt

Device Description: The RF Surgical Systems Inc. Detection System consists of:

1. The Power/Control Console contains the electronics that power and control the detector/scanner. The console also includes the user interface for system operation and communication of the system status, operation and alarms to the user.
2. The Transponder/Tag is a single use electrically passive device that is designed to radiate a magnetic signature when stimulated by magnetic impulses from the detector/scanner.The tag does not store or communicate any information or unique code and is to be mechanically attached to guaze\sponges at the manufacturing site and processed as part of the item
3. The Detection Wand is a transceiver type antenna designed to stimulate the transponder tag assembly with magnetic impulses and then detect the resultant magnetic signature from the tag. The Power/Control Console provides the power and control to the detection scanner. The detection scanner is intended and designed to be a single-use disposable device and will be supplied in a sterile condition as it will enter the surgical field.

K062642
2/3

Intended Use:

The RF Surgical Systems Inc. Detection System is intended to provide a non-invasive means of locating retained surgical sponges, gauze and other tagged items within a surgical site. It is to be employed as an adjunctive detection method to current surgical sponge and gauze counting systems and methods

The indications are similar those of the predicate devices i.e. "for efficient counting and containment of lap sponges, and for constant visibility for assessing blood loss and counting of sponges."

Technological Characteristics:

The RF Surgical Systems Inc. Detection System is analogous to the predicate devices. The Transponder Tag identifies the sponge or gauze to the detection system via a specific radio frequency signal through the single use detection wand. The detection wand can read the tag signal through blood, bodily fluids and the body wall. The 3 element detection system is designed to detect tagged objects(s) within a minimum range of 16" from the detector aperture surface into a patient of average size Tags outside of the patient and more than 36" outside of the scan area must not result in false positives. The console is a durable electro-mechanical assembly that is powered by standard line voltage: 120V, 60Hz and has been designed to work in standard operating rooms or other clinical environments. The console 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

The wand is a transceiver type antenna designed to stimulate the transponder tag assembly with magnetic impulses and then detect the resultant magnetic signature from the tag. The Power/Control Console provides the power and control to the detection scanner.The detection scanner is intended and designed to be a single-use disposable device and will be supplied in a sterile condition as it will enter the surgical field.The Scanner consists of two-part plastic handle that encloses a wire loop antenna, a capacitor and a fuse. The antenna consists of and arrangement of multiple turns of a copper magnet wire with a specific diameter. The copper magnet wire is insulated with an enamel coating. An electrical fuse and series capacitor is wired between the ends of the antenna winding. The antenna is attached to a standard RG-58 50Ω coaxial cable with a standard 50Ω BNC Connector.

The tag is an electrically passive device that is designed to radiate a magnetic signature when stimulated by magnetic impulses from the detector/scanner. The tag does not store or communicate any information or unique code, rather it responds at its resonant frequency, which by design falls within a specific band of operation and which the detection system is designed to identify . All tags resonate at the same frequency within the band of operation, and only the presence of a tag is indicated even should more than one be present.

000056

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 RF Surgical Detection System performed as intended. Animal studies using large swine species further substantiate the satisfactory performance of the detection system. 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 RF Surgical Systems Inc. Detection 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,

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

RF Surgical Systems, Inc.
% Mr. Kevin Cosens
President & CEO
2700 Richards Road, Suite 204
Bellevue, Washington 98005

NOV - 2 2006

Re: K062642
Trade/Device Name: RF Surgical Systems Inc. Detection System
Regulation Number: 21 CFR 880.2740
Regulation Name: Surgical sponge scale
Regulatory Class: I
Product Code: LWH
Dated: September 1, 2006
Received: September 6, 2006

Dear Mr. Cosens:

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

K062642

Intended Use Statement

510(k) Number (if known): K062642

Device Name: RF Surgical Systems Inc. Detection System

Indications for Use:

The RF Surgical Systems Inc. Detection System is intended to provide a non-invasive means of locating retained surgical sponges, gauze and other tagged items within a surgical site. It is to be employed as an adjunctive detection method to current surgical sponge and gauze counting systems and methods

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K062642

000051