K100551
1/4

IV. 510(K) SUMMARY

510(k) SUMMARY (21 CFR 807.92)
ORLocate™ System

AUG 12 2010

510(k) Owner:	Haldor Advanced Technologies Ltd. 2 Habanai st., Hod Hasharon, 45319 Israel Tel: +972 9 788 5867 Fax: +972 9 788 5861
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Date Prepared:	Feb. 20th 2010
Trade Name:	ORLocate™ System
Common:	Surgical Items Counting System
Classification Name:	Surgical sponge counter, Class I, 21 CFR 880.2740, LWH Nonabsorbable gauze for internal use, Class I, 21 CFR 878.4450, GDY
Predicate Devices:	Clearcount Medical SmartSponge K071355 RF Surgical Systems Inc. detection system, K062642 SurgiCount Medical, Inc. Safety-Sponge System, K060076

Device Description:

Haldor ORLocate™ system is an RFID system providing a solution that enables the enumeration of sponges and surgical manual instruments, utilizing passive tags[1] for keeping track of the items during surgery and to identify counting problems. In addition, the system provides a non-invasive means of locating retained surgical items within a surgical site.
The submission consists of the ORLocate™ system which includes: cart and antennas. Additionaly the submission includes accessories which are: associated single use surgical sponges, gauzes, pads and surgical towels each fitted with a uniquely coded RFID tag and uniquely coded RFID tag used for surgical instruments. The RF frequency the system uses is 13.56 MHz according to ISO 15693.
The system supplies also a semi-automatic application to help in counting untagged items, the count information is first entered manually and the calculations are automatic.
From this point on the system cart and antennas will be referred to as the "ORLocate™ system," sponges fitted with Haldor RFID tag will be referred to as "RFID tagged sponge" or "RFID tagged item" and a manual surgical instrument fitted with Haldor RFID tag will be referred to as "RFID tagged surgical instrument" or "RFID tagged item" too.

The system detects each RFID tagged item placed on top of the system antennas prior to surgery and creates an inventory of all sponges (e.g, gauzes, pads) and instruments. The user can also register new items during surgery and the inventory is updated automatically after the new items are scanned in an RFID antenna. The system performs automatic count of all inventory every 5 minutes and also performs count upon user request.

At the end of the procedure, final counts are provided by the system and in the case that any items are missing the mobile antenna may be used to search the surgical site for the retained RFID tagged item.

Intended Use:

The ORLocate™ system is indicated for use in recording and counting the number of RFID-tagged surgical sponges, laparotomy sponges, towels and other tagged items used during surgical procedures in which counting is required. In addition, the product is indicated for providing a non-invasive means of detecting retained RFID-tagged surgical sponges, towels and other tagged items within a surgical site, as an adjunctive detection method to current surgical counting systems and methods.

The indications are similar to those of the predicate device ClearCount SmartSponge system: "for use in counting and recording the number of RFID tagged surgical sponges, laparatomy sponges and towels used during surgical procedures." The

indications are also similar to those of the predicate device RF Surgical Systems Inc. Detection System: "intended to provide a non-invasive means of locating retained surgical sponges, gauze and other tagged items within a surgical site."

Technological Characteristics:

The ORLocate™ System is analogous to the predicate devices. Similar to the ClearCount SmartSponge System and the RF Surgical Systems Inc. Detection System, the system is comprised of a cart that contains the computer, processing units and connected antennas which can detect tags via a specific radio frequency signal. The tags are attached to surgical sponges and surgical instruments to enable the enumeration of the items. The RFID tag is securely sewn to each sponge, gauze or towel in the same manner as in the ClearCount SmartSponge System. A second type of RFID tag is securely attached to surgical instruments The mobile antenna in RF Surgical and the ORLocate™ system can read the tag signal through blood, bodily fluids and the body wall.

The customized software program, similar to the predicate software for the ClearCount SmartSponge System, uses the scanned and recorded information to count the number of items at the beginning of a surgical procedure, during and then again before surgical closure. A count can be obtained on demand from the computer and locates each item in antenna range. The count at the end of the surgery can be helpful in determining if any sponges are missing and may still be inside a patient.

Non-Clinical Performance Data:

Non-clinical testing included demonstrating performance of system and tagged items in laboratory tests. Tests demonstrated biocompatibility of tagged items, and permanent attachment of the tags to both sponges and instruments. The validated software functioned as intended under simulated use, properly counting sponges in body fluids. Test results also demonstrate the RFID tagged sponges and instruments are as safe as the predicate devices and the software installed on the system cart computer provides an added measure of safety and effectiveness to current methods of sponge and instrument counting presently used in the surgical and clinical environments. Pertinent testing done on this device include: system interference with operating room devices, ORLocate sponge X-ray detection, ORLocate Tag pull test, counting accuracy test, electromagnetic compatibility testing per IEC 60601-1-2:2007 and electrical safety testing per IEC 60601-1:1988 + A1:1991 + A2:1995 and EN 60601-1:1990 + A1:1993 + A2:1995 + A3:1996. The testing supports a determination of substantial equivalence to products and technologies previously cleared by FDA.

Conclusions:

In conclusion, the ORLocate system and accessories are substantially equivalent to the predicate devices identified. In addition, non-clinical performance data and test results demonstrate

the product is as safe and effective for its intended use as its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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AUG 12 2010

Re: K100551
Trade/Device Name: ORLocate™ system
Regulation Number: 21 CFR 880.2740
Regulation Name: Surgical sponge scale
Regulatory Class: I
Product Code: LWH
Dated: June 17, 2010
Received: June 23, 2010

Dear Sarit Gelbart Gal-Rom:

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

K100551

III. INDICATIONS FOR USE STATEMENT

Indications for Use

AUG 12 2010

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

Device Name: ORLocate™ system

Indication for use: The ORLocate™ system is indicated for use in recording and counting the number of RFID-tagged surgical sponges, laparotomy sponges, towels and other tagged items used during surgical procedures in which counting is required. In addition, the product is indicated for providing a non-invasive means of detecting retained RFID-tagged surgical sponges, towels and other tagged items within a surgical site, as an adjunctive detection method to current surgical 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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MXM

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

510(k) Number K100551