510(k) SUMMARY
MST AutoLap System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

MST – Medical Surgery Technologies Ltd.
Kochav Yokneam Building, POB 685,
Yokneam Ilit 20692, Israel

Phone: +972-73-796-5570
Facsimile: +972-73-796-5571
Contact Person: Tami Harel
Date Prepared: August 21, 2013

Name of Device and Name/Address of Sponsor

AutoLap System
MST – Medical Surgery Technologies Ltd.
Kochav Yokneam Building, POB 685,
Yokneam Ilit 20692, Israel

SEP 19 2013

Common or Usual Name

Laparoscope Holder

Classification Name

Laparoscope, General and Plastic Surgery
21 C.F.R. 876.1500, Product Code GCJ

Predicate Devices

LapMan Laparoscope Manipulator System and Accessories, Manufactured by MEDSYS, S.A. (K062968)

Intended Use / Indications for Use

The AutoLap System is indicated for General laparoscopic, Gynecologic and Urologic procedures for the purpose of holding and controlling the movement of a standard laparoscope or rigid endoscope within surgical cavities during minimally invasive laparoscopic surgery.

Technological Characteristics

The AutoLap System is designed to hold and control the movement of a laparoscope or rigid endoscope during laparoscopic procedures. The AutoLap System includes both software and hardware. Hardware components include a Processing Unit, which includes the system's electronics and software algorithms, a Base Unit and a Laparoscopic Unit that include motors and sensors. The Base Unit is mounted on the operating bed. An

accessory cart that is used for placing the system's components during the procedure and their storage afterwards is also provided.

To maneuver the laparoscope to the desired position, the surgeon presses a single button, referred to as Command Unit, which is affixed to his/her hand or to the surgical instrument and transmits RF signals to the system. Additionally, the system enables the surgeon to manually perform larger movements of the laparoscope using the Manual Activation Button affixed to the AutoLap system. Movements can be performed in the left/right, up/down and zoom in/ zoom out directions.

Performance Data

The following testing was conducted to evaluate the device:

- Electrical safety was tested in accordance with ANSI/AAMI 60601-1:2005 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

- Electromagnetic Compatibility (EMC) was tested in accordance with IEC 60601-1-2:2007 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.

- Sterilization validation was conducted in accordance with the ISO 11135-1 and 10993-7 standards.

- Packaging integrity and shelf life validation in accordance with ISO 11607-2 and ASTM D1649-09.

- Bench testing was conducted in order to demonstrate that the AutoLap system performs according to its requirements and specifications. Performance in terms of movement velocities in all DOF, movement range in all DOF, directional movement control and image stability, have all been demonstrated. Safety features such as Emergency Stop Button functionality and warning messages have all been demonstrated to meet their respective acceptance criteria.

- The company performed an animal study evaluating the use of the AutoLap system in laparoscopic cholecystectomy and Nissen fundoplication on domestic pigs. Procedures were performed by several surgeons. No operative complications related to the use of the AutoLap were observed and the device met all predefined acceptance criteria. The results demonstrated the system's performance and safety. The system's performance in terms of the movement control was validated.

All performance testing demonstrates that the AutoLap System performs according to specifications and functions as intended.

Substantial Equivalence

The AutoLap System is substantially equivalent to the LapMan Laparoscope Manipulator System and Accessories. The AutoLap System has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the AutoLap System and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the AutoLap System is as safe and effective as the LapMan Laparoscope Manipulator System and Accessories. Thus, the AutoLap System is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

September 19, 2013

Medical Surgery Technologies, Ltd.
c/o John Smith, M.D., J.D.
Partner
Hogan Lovells US LLP
555 Thirteenth Street NW
Washington DC 20004

Re: K131375
Trade/Device Name: AUTOLAP
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: August 21, 2013
Received: August 21, 2013

Dear Dr. Smith:

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 contact 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. 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,

David Krause -S

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

Enclosure

Indications for Use Statement

510(k) Number (if known): K131375

Device Name: AUTOLAP

Indications for Use:

The AutoLap System is indicated for General laparoscopic, Gynecologic and Urologic procedures for the purpose of holding and controlling the movement of a standard laparoscope or rigid endoscope within surgical cavities during minimally invasive laparoscopic surgery.

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)

Long H. Chen -A Digitally signed by Long H. Chen -A DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -A, 0.9.2342.19200300.100.1.1=1300369056 Date: 2013.09.18 07:04:48 -04'00' for MXM

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K131375