DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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M.S.T. Medical Surgery Technologies Ltd
% John Smith, M.D., J.D.
Regulatory Counsel
Hogan Lovells Us LLP
555 Thirteenth Street NW
Washington, District of Columbia 20004

November 17, 2015

Re: K152848
Trade/Device Name: Autolap System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: September 29, 2015
Received: September 29, 2015

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement on last page*

510(k) Number *(if known)*

K152848

Device Name

AutoLap

Indications for Use *(Describe)*

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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) SUMMARY

## MST's AutoLap

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

M.S.T Medical Surgery Technologies Ltd.
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Yokneam Ilit 2069200, Israel
Phone: +972-73-796-5570
Facsimile: +972-73-796-5571
Contact Person: Tami Harel

Date Prepared: November 12, 2015

**Name of Device and Name/Address of Sponsor**
AutoLap System
M.S.T Medical Surgery Technologies Ltd.
Kochav Yokneam Building, Floor 5,
Yokneam Ilit 2069200, Israel

**Common or Usual Name**
Laparoscope Holder

**Classification Name**
Laparoscope, General and Plastic Surgery

**Predicate Devices**
AutoLap manufactured by M.S.T. Medical Surgery Technologies (K131375)

**Purpose of the 510(k) notice**
The AutoLap is a modification to the cleared AutoLap device**.**

**Indications for Use Statement**
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 and 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. The movement of the laparoscope may be controlled as a simple joystick, enabling movements to up/down, left/right, zoom in/ zoom out directions or be guided by the movement of a designated tool within the field of view, enabling movement in oblique trajectories. Additionally, the system enables the surgeon to manually perform larger movements of the laparoscope using the Manual Activation Button affixed to the AutoLap system.

**Performance Data**

The following testing was repeated to evaluate the modified 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.

- Bench testing was conducted in order to demonstrate that the AutoLap system performs according to its requirements and specifications. Testing evaluated the following:
    - Image stability
    - Image processing, system functionality, and performance to move the camera to the requested position using different modes of operation"
    - Connection, receipt and display of video Connection and display on separate monitor

- Animal testing demonstrated the performance of the added mode of movement control.

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

**Substantial Equivalence**

The modified AutoLap system has the same intended use and indications, similar principles of operation, and technological characteristics as the cleared AutoLap system. The modified AutoLap includes an additional mode of operation that can be selected by the surgeon which allows for laparoscope camera movement to be controlled by the movement of a designated tool within the field of view. Additionally, the modified AutoLap includes means for the connection of a separate monitor to allow for a parallel display. The minor differences in the modified AutoLap technological characteristics do not raise any new or different questions of safety or effectiveness. Performance data demonstrates that the modified AutoLap system is as safe and effective as the cleared AutoLap device. Thus, the modified AutoLap system is substantially equivalent to its predicate devices.