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

March 24, 2016

THD LAP
Ms. Einat Duvdevany
General Manager
1 Nirim St.
Tel Aviv, Israel

Re: K153202
Trade/Device Name: iMESH Tacker
Regulation Number: 21 CFR 878.4750
Regulation Name: Implant staple
Regulatory Class: Class II
Product Code: GDW
Dated: February 23, 2016
Received: February 25, 2016

Dear Ms. Duvdevany:

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" (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 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,

David Krause -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 below.

510(k) Number *(if known)*
K153202

Device Name
iMESH Tacker

Indications for Use *(Describe)*
The iMESH Tacker is indicated for fixation of prosthetic material to soft tissue in various minimally invasive and open general surgical procedures, such as hernia repair.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

Special 510(K) Summary

THD Lap Ltd's modified *iMESH Tacker* (IMT)

Date Prepared: 20 October, 2015

510(k) owner name:

Company name: THD Lap Ltd
Address: 1st Nirim St.
Tel Aviv
Israel
Phone: +972-52-6717051
Fax: +972-3-5037673
E-mail: Einat.Duvdevany@thdlap.com

Contact person:

Name: Tali Hazan
Address: Ramot-Naftali, 13830
Israel
Phone: +972-50-5292304
Fax: +972-72-2448981
E-mail: tali.hazan@talmed.co.il

Device Name:

Common or usual name: Implantable Staple
Proprietary/Trade name: iMESH Tacker

Classification name iMESH Tacker has been classified as **Class II** device under the following classification name:

Name	Product Code	21 CFR Ref.	Panel
Staples, implantable	GDW	878.4750	General & Plastic Surgery

Predicate Device:

The modified iMESH Tacker is substantially equivalent to the originally legally marketed iMESH Tacker which was cleared under 510(k) number **K110728**.

Device description:

Like the original iMESH Tacker, the modified iMESH Tacker is a sterile, single use device for the fixation of prosthetic material, such as a hernia mesh, onto soft tissue. The applicator features an articulating tip. The absorbable tack is made of synthetic polyester derived from a lactic acid and glycolic acid copolymer (PLA/PGA).
The modified device's implantable Tack is violet colored. The Applicator is pre-loaded with up to 30 Tacks.
The iMESH Tacker is comprised of 3 parts:

- An in-line handle,
- A shaft with an articulating tip
- The bio-absorbable Tacks

The modified iMESH Tacker is identical to the original iMESH Tacker with the exception of a change in the color of the tacks to violet, several minor internal changes and slight changes to packaging and certain components. We believe that none of these changes affect the substantial equivalency determination of the device with its predicate device.

Intended use:

The iMESH Tacker is indicated for fixation of prosthetic material to soft tissue in various minimally invasive and open general surgical procedures, such as hernia repair.

Technological characteristics and Substantial Equivalence:

The modified IMT is substantially equivalent with the original IMT cleared under K110728 as identified above under 'predicate device' section.
Both new and predicate device have the same indications for use, same shape, design and characteristics. All changes that differs the new device from the original device (predicate) were fully addressed and evaluated.

The substantial equivalence table is following presented:

Feature	**iMESH Tacker - Predicate Device (K110728) -**	**Modified iMESH Tacker - New Device -**
Indication for use	The iMESH Tacker is indicated for fixation of prosthetic material to soft tissue in various minimally invasive and open general surgical procedures, such as hernia repair.	The iMESH Tacker is indicated for fixation of prosthetic material to soft tissue in various minimally invasive and open general surgical procedures, such as hernia repair.
Single use	Yes	Yes
Supplied sterile	Yes	Yes
Materials	Same or Similar	Same or Similar
Environment of use	Hospitals, sub-acute care institutions and surgery centers	Hospitals, sub-acute care institutions and surgery centers
Patient population	Individuals undergoing procedures where prosthetic mesh is being used.	Individuals undergoing procedures where prosthetic mesh is being used.
Delivery Device Design	Handle with triggers	Handle with triggers
Tip design	Articulating tip	Articulating tip
Tacks pre-loaded in tip	Yes	Yes
Tip material	Stainless steel	Stainless steel
Number of tacks pre-loaded	30	30
Tack shape	Helical	Helical
Biocompaibility	Yes	Yes
Technology	Manual	Manual
Mode of operation	Tack insertion using the Tacker	Tack insertion using the Tacker
Tack material	PLA/PGA	PLA/PGA
Tack color	Non-colored (Transparent/Natural)	Violet
Performances	Same (equivalent)	Same (equivalent)

Non-clinical performance data:

The following non-clinical tests were performed:

- Strength Testing
- Functional Testing
- In-vivo Degradation Tests
- Mechanical testing
- Use simulation test
- Endotoxin testing
- Shelf life using real-time aging

The device passed all tests and successfully met all acceptance criteria.

Conclusions:

The evaluation of the THD Lap Ltd's Modified iMESH Tacker Device non-clinical tests, demonstrate that the device is as safe and as effective as the predicate device and that all performance tests' acceptance criteria were met. Therefore, we believe it is substantially equivalent to the iMESH Tacker legally marketed devices previously cleared.