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JUN - 8 2011

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Official Contact: Einat Duvdevany - CEO

Proprietary or Trade Name: iMESH Tacker

Common/Usual Name: Implantable staple

Classification Name/Code: GDW – Implantable staple
CFR 878.4750

Device: iMESH Tacker

Predicate Devices: K090470 – Covidien – Protack
K071061 – Sorbx (Covidien) – Absorbatack

Device Description:
The 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. The Applicator is pre-loaded with 30 tacks.

Indications 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.

Patient population:
Individuals undergoing procedures where prosthetic mesh is being used.

Environment of Use:
Hospitals, sub-acute care institutions, and surgery centers.

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Comparison to Predicates

	iMESH Tacker	Covidien Absorbatack K071061	Covidien Protack K090470
Product Classification	GDW	GDW	GDW
CFR	874.4750	874.4750	874.4750
Indications for Use	For fixation of prosthetic material to soft tissue in various minimally invasive and open general surgical procedures, such as hernia repair	For fixation of prosthetic material to soft tissue in various minimally invasive and open general surgical procedures, such as hernia repair	For use in affixing prosthetic material or approximately tissue. May be used both endoscopically and in open procedures
Environments of Use	Hospitals, sub-acute care institutions, and surgery centers.	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.	Individuals undergoing procedures where prosthetic mesh is being used.
Delivery Device Design	Handles with triggers	Handles with triggers	Handles with triggers
Tip design	Articulating tip	Non-articulating tip	Non-articulating tip
Tacks pre-loaded in tip	Yes	Yes	Yes
Material of tip	Stainless steel	Stainless steel	Stainless steel
# of Tack pre-loaded	30	10 and 20	30
Tack Design	Helical	Screw	Helical
Tack shape	Bio-Absorbable	Bio-Absorbable	Non-bio-Absorbable
Tack Length	6.3 mm	5 mm	3.8 mm
Material of Tack	PLA/PGA	PLA/PGA	Titanium
Packaging	Sterile	Sterile	Sterile
Single patient use, disposable	Yes	Yes	Yes
Performance Testing			
Fixation Force	On implantation 17.07 N	On implantation 16.46 N	Not tested
	After 14 days 18.82 N	After 14 days 8.35 N	Not Tested
Fixation Force Mid-section average, upper and lower sections average	17.06 17.08	11.50 22.113	Not tested

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Summary of substantial equivalence:
We have demonstrated that the iMESH Tacker is equivalent to the predicates in design and performance characteristics:

The iMESH Tacker is viewed as substantially equivalent to the predicate devices because:

Indications –

- Identical indications for use - indicated for fixation of prosthetic material to soft tissue in various minimally invasive and open general surgical procedures, such as hernia repair to predicate – K071061 – Absorbatack

Technology –

- Similar technology which incorporates, an in-line handle, a tip and pre-loaded tacks – K071061 – Absorbatack
- Similar tack design – helical – K090470 - Protack

Materials –

- Identical materials to predicate – K071061 – Absorbatack

Environment of Use –

- Identical to predicate – K071061 – Absorbatack

Performance specifications –

- Degradation and consistency of fixation force were tested and found to be similar to predicate – K071061 – Absorbatack

Differences –
The only difference between the proposed iMESH Tacker and the predicates is:

- Helical, bio-absorbable tack and
- Deployment device, the iMESGH Tacker, has an articulating tip to help facilitate tack placement.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

EasyLap Ltd.
% PreMedic, Inc.
Mr. Paul Dryden
24301 Woodsage Drive
Bonita Springs, Florida 34134

JUN - 8 2011

Re: K110728
Trade/Device Name: iMESH Tacker
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: May 29, 2011
Received: June 1, 2011

Dear Mr. Dryden:

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,

For Mark N. Melkerson 6/8/11

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

Enclosure

Indications for Use Statement

510(k) Number: K110728 (To be assigned)

Device Name: iMESH Tacker

Indications 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.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MXM

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

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