K101218

JUN 17 2010

Pre Market Notification Submission – 510(k)

510(K) SUMMARY
PatchAssist Device
510(k) Number K_____

Company Name

PolyTouch Medical Ltd.
Misgav Venture Accelerator M.P. Misgav
20174, Israel
Tel: 972-72-260-7066
Fax: 972-72-260-7266

Contact Person

Leo Basta
NorthStar Biomedical Associates for
PolyTouch Medical Ltd.
755 Westminster Street Unit 120
Providence, RI 02903
617.834.9866 (phone)
401.454.1733

And/or
Orly Maor
25 A Sirkin Street
Kfar-Saba 44421, Israel
Tel: 972-7453607
Fax: 972-153-9-7453607

Trade/Proprietary Name

PatchAssist device

Classification Name

Laparoscope, General & Plastic Surgery

The PatchAssist device is a single use device that will be provided sterile.

Performance Data

The PatchAssist device underwent a full battery of bench tests and animal studies to demonstrate its safe and effective performance in delivering, deploying and placing, the hernia mesh. In addition, usability testing was conducted. It was concluded that the device facilitates the attachment of the mesh to the abdominal wall and is easily withdrawn from the abdominal cavity.

The testing demonstrated that the PatchAssist device is a safe and effective device for facilitating the delivery of soft tissue prosthetics during the laparoscopic repair of hernia without raising any new safety or effectiveness issues.

Conclusion:
PolyTouch Ltd. believes that, based on the information provided in this submission, the PatchAssist device is substantially equivalent to its predicate devices.

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

JUN 17 2010

PolyTouch Medical Ltd.
% NorthStar Biomedical Associates
Mr. Leo Basta
755 Westminster Street, Unit 120
Providence, Rhode Island 02903

Re: K101218
Trade/Device Name: PatchAssist device
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: ORQ
Dated: April 29, 2010
Received: April 30, 2010

Dear Mr. Basta:

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

Indications for Use

510(k) Number (if known): K101218

Device Name: PatchAssist device

The PatchAssist device is intended to be used to facilitate the delivery of soft tissue prosthetics during the laparoscopic repair of soft tissue defects (e.g. hernia repair).

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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

510(k) Number K101218