K103269
Page 1/3

510(K) SUMMARY

PolyTouch Medical Ltd.

PatchAssist™

NOV 2 3 2010

7.1.1 Applicant's Name:

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

7.1.2 Contact Person:

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

7.1.3 Date Prepared: November 1, 2010

7.1.4 Trade Name: PatchAssist™ Large

7.1.5 Classification Name: Surgical mesh deployer

7.1.6 Classification: Class II; Product Code ORQ ;
Regulation No. 878.3300
Panel: General and Plastic Surgery Devices

7.1.7 Predicate Devices: PolyTouch Medical Ltd. PatchAssist™ device cleared under K101218.

7.1.8 Device Description:

The PatchAssist™ device is used to facilitate the delivery of mesh during the laparoscopic hernia repair. Essentially, it is a tray like device that holds the mesh under the hernia allowing the surgeon to connect the mesh to its proper place.

The PatchAssist™ device are manual laparoscopic surgical instrument. The surgeon connects a standard hernia mesh (not part of the PatchAssist™ device) to the device using a dedicated stapling apparatus furls the mesh on the device deployment section (as it is done in a standard procedure) and inserts it into the abdominal cavity through a standard laparoscopic port (trocar). Once inside the abdominal cavity, the device enables the surgeon to rapidly maneuver the mesh into position over the hernia defect by providing a rigid frame onto which the mesh is attached and placing the mesh over the desired location so that it may then be attached to the surgical location. The mesh is connected to the tissue using the same technique as currently performed by the surgeon (e.g., hernia tacks). Upon mesh fixation to the tissue, the surgeon releases the mesh from the deployment frame and extracts the device from the abdominal cavity leaving the fixated mesh in its desired location. The PatchAssist™ Large is another model of the PatchAssist™ that has a slightly larger deployment frame to facilitate the insertion of large size meshes.

7.1.9 Intended Use:

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).

7.1.10 Performance Standards:

No performance standards have been established for such device under Section 514 of the Federal Food, Drug, and Cosmetic Act.

7.1.12 Performance Data & Substantial Equivalence

The PatchAssist™ Large is substantially equivalent in all aspects, e.g., technological characteristics, mode of operation, performance characteristics, intended use, etc., to the PolyTouch Ltd.'s commercially available PatchAssist™ device cleared under K101218.

The change between the devices is in the size of the deployment frame. The slightly larger size enables deployment of varaity of mesh sizes including large size meshes from 15x15cm up to 38x28cm.

A series of performance testing were performed to demonstrate that the PatchAssist™ Large does not raise any new questions of safety and efficacy. These tests includes:

- Mesh Rolling and Insertion using the PatchAssist™ Large Device
- Articulation and Maneuverability Test
- PatchAssist™ Large Performance Evaluation

Based on the risk analysis performed and these tests results, PolyTouch Medical Ltd. believes that the PatchAssist™ Large is substantially equivalent to the cleared PatchAssist™ device and does not raise any new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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

NOV 2 3 2010

Re: K103269
Trade/Device Name: PatchAssist™ Large
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: ORQ
Dated: November 1, 2010
Received: November 4, 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 STATEMENT

K103269

510(k) Number (if known): Not known at this time

NOV 2 3 2010

Device Name: **PatchAssist™ Large**

Indications for Use: 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 ___√___ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (Part 21 C.F.R. 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

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

510(k) Number K103269