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APR 21 2008

510(K) SUMMARY

EndoGun Medical Systems Ltd
EndoFast Reliant™ System

6.1.1 Applicant's Name:

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Israel, 42880
Tel: +972 (9) 8987033
Fax: +972 (9) 8987119
Email: noga@endogun.com

6.1.2 Contact Person:

Dorit Winitz, Ph. D
Biomedical Strategy (2004) Ltd.
Moshe Aviv Tower, 34th Floor,
7 Jabotinsky Street
Ramat Gan 52520, Israel
Tel: +972-3-612-3281
Fax: +972-3-612-3282
dorit@ebms.co.il

6.1.3 Date Prepared:

March, 2008

6.1.4 Trade Name:

EndoFast Reliant™ System

6.1.5 Common Name:

Minimal invasive fastening device with surgical polymenric mesh.

6.1.6 Classification:

21 CFR 876.1500, 21 CFR 878.3300
Class:II
KOG and GCI (Endoscope and accessories).
FTL (Mesh, Surgical Polymeric)

6.1.7 Predicate Devices

EndoGun EndoFast Reliant™ Susyem, clered under K060329.

6.1.8 Device Description:

The EndoFast Reliant™ System is a sterile, single use system, consisting of the following componnents:

1. Plastic Fixation Devices (X5) and a Handle. Each Fixation Device is preloaded with a Spider Fastener.
   The Spider Fastener is provided with a Retrieval Unit, which together with the Extraction Device (described below), enables facile retrieval of the deployed Fastener when needed.
2. A plastic Extraction Device, provided for easy removal of the Fastener when needed, under direct vision.
3. Polypropylene monofilament Surgical Mesh

6.1.9 Intended Use:

The EndoFast Reliant™ System is indicated for fixation of surgical mesh to tissues for tissue reinforcement during minimally invasive procedures.

6.1.10 Performance Data & Substantial Equivalence

The EndoFast Reliant™ System is substantially equivalent in all aspects, e.g., technological characteristics, mode of operation, performance characteristics, intended use, etc., to the commercially available EndoFast Reliant™ System, cleared under K060329.

The principle changes between the devices include:

1. The materials of the Fixation Device and the Extraction Device were changed from stainless steel to plastic (the material of the stainless steel Fastener were not changed).
2. The Fixation Device was angulated in its distal end.
3. A separate handle was added to the Fixation Device, thus discharge of the Fastener can be accomplished only after the Fixation Device is locked in the Handle.
4. The Extraction mechanism was changed to include a thread guided mechanism.
5. The pacakging of the device was changed to blister packaging.
6. The flat polypropylene monofilament surgical mesh is provided pre-cut in two shapes instead of one rectangular shape, to better suit different anatomies. The mesh with the 4 pouches at the corners is not used with the modified device.

A series of safety and performance testing, including bench testing were performed to demonstrate that the modified EndoFast Reliant™ System does not raise any new questions of safety and efficacy. These tests include:

- Performance testing, including the reliability and insertion force test of the Fixation Device and Handle and the Fastener, the reliability of the Fastener in expending and holding forces (pullout strength), the Extraction Device with Thread Reliability and force test, and the Cadaver study.
- Biocompatibility testing.
- Sterility and packaging testing.

Based on these tests results, EndoGun Medical Systems Ltd. believes that the modified EndoFast Reliant™ System is substantially equivalent to the cleared EndoFast Reliant™ System without raising new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 21 2008

Endogun Medical Systems
% Biomedical Strategy
Dorit Winitz
Jabotinsky St 7
Ramat Gan 52520 Israel

Re: K080836
Trade/Device Name: EndoFast Reliant™ System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: March 19, 2008
Received: March 25, 2008

Dear Dorit Winitz:

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.

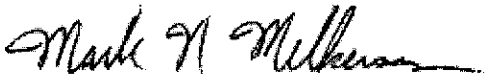
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K080836

Device Name: EndoFast Reliant™ System

Indications for Use:

The EndoFast Reliant™ System is indicated for fixation of surgical mesh to tissues for tissue reinforcement during minimally invasive procedures.

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

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080836