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510(K) SUMMARY
PREPARED AUGUST 13, 2006
EndoFast Reliant System

SEP 11 2006

Applicant's Name: Endogun Medical Systems
12 Haplada St.
South Industrial Park
Kiryat Shmona 11013
ISRAEL
Tel (972)4-681-8801
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Contact Person: Yoram Levy, Qsite
31 Haavoda St.
Binyamina, Israel 30500
Tel (972)4-638-8837; Fax (972)4-638-0510
Yoram@qsitemed.com

Product Name: EndoFast Reliant

Common Name: Minimal invasive fastening device with surgical polymeric Mesh

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

Device Description: The *EndoFast Reliant System* is a sterile, single use system consisting of the following components:

- A stainless steel Fixation Device preloaded with the Spider Fastener. The Fixation Device is provided with a safety pin that prevents inadvertent deployment of the Spider Fastener.
- Surgical Mesh; Polypropylene mono-filament Mesh
- A stainless steel Extraction Device; provided for easy removal of the Spider Fastener when needed under direct vision.

Endogun's *EndoFast Reliant System* is used to attach or reinforce tissues by fastening them with Spider Fasteners. These Fasteners

will attach a suitably designed mesh onto the tissue to ensure fixation between two tissues.
The devices are preloaded for single use.
The *EndoFast Reliant System* is supplied sterilized and ready for use upon removal from its packaging.
The Fixation Device is provided with a safety pin that prevents inadvertent deployment of the Spider Fastener.

Intended Use: The EndoFast Reliant System is indicated for **fixation of surgical mesh to tissues for tissue reinforcement during minimally invasive procedures**

Predicate Device: The predicate device for the Fixation Device is: A & A Tacker Endoscopic Stapler (K003949).
The predicate device for the surgical Mesh is AMS Large Pore Polypropylene Mesh (K033636).

Performance Data

The Fixation Device and Fastener were tested for Insertion force, Fatigue testing, Dynamic grip strength, Retraction in response to different tension forces, Rigidity tests, Cyclic loading, Fatigue testing for durability and integrity of the Fastener, Anterior Fixation, Pullout strength, Reliability tests, Fastener spread, Ergonomics and Sterility.
The Extraction Device was tested for its reliability.
The mesh was tested according to the FDA "Guidance for the Preparation of Premarket Notification Application for a Surgical Mesh". The following performance tests were performed on the mesh: Anterior Fixation, Sterility, Thickness, Weave characteristics, Pore size, Mesh density, Tensile strength, Pullout strength, Burst strength, Tear resistance, Fatigue and Flexibility.
Results of this testing indicate that the EndoFast Reliant System is substantially equivalent to the predicate devices.

Performance Testing - animal

A series of animals were implanted with the EndoFast device in order to evaluate the safety and effectiveness of using the ***EndoFast Reliant*** as a tissue reinforcing system. Altogether five different experiments were conducted using 4 sheep (2 before sacrifice) and a pig as an animal model. Two of the sheep studies included two months of follow-up. Following animal sacrifice, the pathological effects on tissues were assessed by histological examination.

The animal study established the safety and efficacy of using the ***EndoFast Reliant*** as a tissue reinforcing system. Specially, this study demonstrated that the ***EndoFast Reliant*** device is safe for its intended use, it is easy to introduce, the insertion procedure is simple, fast and the anchoring is effective.

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Comparison with Predicate Devices:

The EndoFast System provides an approximation of soft tissues and fixation of surgical mesh to tissues similar to the cleared A & A Tacker Endoscopic Stapler (K003949) except for some differences in the insertion technique and the structure. The EndoFast's Mesh is substantially equivalent to AMS Large Pore Polypropylene Mesh (K033636). The performance and differences were tested for safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 6 2006

Endogun Medical Systems
% Yoram Levy
31 Haavoda Street
Binyamina, Israel 30500

Re: K060329
Trade/Device Name: EndoFast Reliant System
Regulation Number: 21CFR §878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: September 11, 2006
Received: September 11, 2006

Dear Mr. Levy:

This letter corrects our substantially equivalent letter of September 11, 2006.
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 (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.

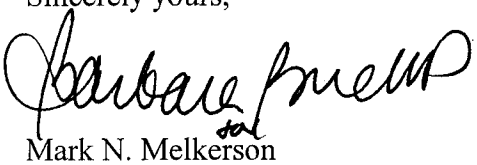
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 continue 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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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/dsma/dsmamain.html

Sincerely yours,



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

Enclosure

K060329

510(k) Number (if known): K060329

Device Name: EndoFast Reliant

- **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 __x__ AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____ (21 CFR 801 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 Cardiovascular, Respiratory and Neurological Devices
510(k) Number

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

510(k) Number K060329