510(k) summary of Safety and Effectiveness
NeatStitch Laparoscopic Closure device

1. **Sponsor name**

NeatStitch Ltd.
Hahadas 1 St.
POB 132
Or Akiva
Israel 30600
Tel: + 972 4 6262876
Fax: + 972 4 6262877

JAN 12 2007

2. **Device name**

Proprietary name: NeatClose Suturing Device
Common/Usual name: Manual Surgical Instrument for general use.
Classification name: Needle driver
Class I (exempt) 878.4800 (Product code HCF- Instrument, Ligature Passing and Knot tying), Manual surgical instrument for general use
Class II (510(k)) 878.4493 (Product code GAM- Suture, Absorbable, Synthetic polyclycolic acid) Absorbable poly(glycolide/l-lactide) surgical suture.

3. **Identification of Predicate or Legally marketed Device**

FASTCLOSE Suturing Device (K011105)
LSI Solutions Suture Placement Device (K981531)
ATRAMAT and SuperSorb Polyglycolic Acid Surgical Sutures (K040282).

4. **Device description**

The NeatClose Suturing Device has three major component: 1) a reusable Handle, 2) a single-use disposable cartridge (containing a patented needle guides and needles), and 3) a suture. The cartridge (including the pre-loaded suture) is assembled onto the Handle. The device is then inserted through the access site through the port working channel (or without it), the needle guides are deployed and the device is withdrawn till the needle guides contact the inner abdominal wall. Then the needles are deployed, penetrating the tissue and retrieved in the cartridge. Right after, automatically, the needle guides are retracted to the cartridge as well. Then the device is completely withdraws, leaving the suture to be tied by the surgeon as he/she routinely does.

5. Intended use

The NeatClose Suturing Device is intended for the approximation and/or ligation of soft tissues in laparoscopic procedures.

6. Comparison of Technological Characteristics

The NeatClose Suturing Device is substantially equivalent in intended use and/or function to the following predicate devices: FASTCLOSE Suturing Device (K011105), LSI Solutions Suture Placement Device (K981531), and the ATRAMAT and SuperSorb Polyglycolic Acid Surgical Sutures (K040282).
The NeatClose Suturing Device is pre-loaded with a commercial cleared suture.
The intended use of each of the predicate devices is soft tissue approximation and/or ligation of soft tissue. The NeatClose Suturing Device is used for the same intended use of soft tissue approximation and/or ligation as the predicate devices.
The operating principle of the NeatClose Suturing Device is the same as that of the predicate devices: a manual instrument is used to pass needles through tissue for suturing.

7. Performance Testing

The NeatClose Suturing Device performs the same function as a standard needle driver or guide. Since the NeatClose Suturing Device is pre-loaded with a non–sterile thread the suture was tested and showed that the suture characteristics as determined by the suture manufacturer (including degradation) and according to USP, are preserved after sterilization and packaging.
In addition, prototype NeatClose Suturing Device was tested in a controlled animal study with two pigs (another pig was used later as an acute experiment with the use of only Neatstitch device in 6 access ports). The scope of this study was to evaluation the feasibility, safety, efficacy of the NeatClose Suturing Device with compared to hand suturing, and additional three currently marketed devices for suturing of the laparoscopic access site (none of them was one of the predicate devices of this notification). Two pigs were used for this comparison, with 8 access sites in each. The measurements were for ease of use, duration, safety and efficacy.
It was concluded therefore that the NeatClose Suturing Device is a very effective, completely safe, reliable, fast and user-friendly device for the closure of port access in laparoscopic procedures.
The suture from the sterile and packed NeatClose Suturing Device was tested for Sterility (USP general chapter 71), Tensile strength (USP

general chapter 881), Sutures-Diameter (USP general chapter 861) and Suture-Needle Attachment (USP general chapter 871).
The sterilization was validated per international standards.
Packaging and shelf-life validation are in progress and will be completed before commercial marketing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NeatStitch Ltd
% Yossi Muncher, Ph.D.
Vice President, Clinical and
Regulatory Affairs
Hahadas 1 ST.
Or Akiva, Israel 30600

JAN 12 2007

Re: K063462
Trade/Device Name: NeatClose Suturing Device
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable poly(glycolide/L-lactide) surgical suture
Regulatory Class: Class II
Product Code: GAM, HCF
Dated: November 11, 2006
Received: November 22, 2006

Dear Dr. Muncher:

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.

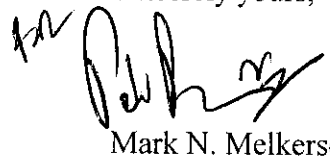
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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 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/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

510(k) number (if known): _____

Device name: NeatStitch NeatClose suturing Device

Indication for use:

The NeatStitch NeatClose suturing device is intended for the approximation and/or ligation of soft tissues in laparoscopic procedures.

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)

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

510(k) Number K063462