SEP 16 2004

510(K) SUMMARY

K041757

Compression Anastomosis Clip (CAC)

1/3

510(k) Number K_____

Applicant's Name:

NiTi Medical Technologies Ltd.
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Netanya 42506, Israel
Tel.: 972-9-865-0610
Fax: 972-9-835-0127

Contact Person:

Orly Maor
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And/or

Jonathan S. Kahan, Esq.
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Tel: (202) 637-5794
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Date Prepared:

June 2004

Trade Name:

Compression Anastomosis Clip (CAC)

Classification Name:

IMPLANTABLE CLIP

K041751

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Classification:

The FDA has classified implantable clip as class II device (product code FZP, Regulation No. 21 C.F.R. § 878.4300) and they are reviewed by the Division of General and Restorative Devices.

Predicate Device:

- Compression Anastomosis Clip (CAC) (NiTi Medical Technologies Ltd.) cleared under K033324.
- Proximate™ Linear Cutter and Stapler (Ethicon Endo-Surgery, Inc. USA) cleared under K843603 and K020779.
- GIA stapler (and Endo GIA) (United States Surgical Cooperation, UAS) cleared under K843603.
- Valtrac Biofregmentable Anastomosis Ring (Devis + Geck) cleared under K881484 and K931056

Performance Standards:

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

Intended Use:

The NiTi CAC (Compression Anastomosis Clip) is intended to be used to facilitate side-to-side anastomosis of the alimentary tract yielding an inverted serosa-to-serosa anastomosis. Once wound strength is sufficient to maintain the anastomosis, the NiTi CAC is passed from the body. The NiTi CAC is not applicable through Trocars in laparoscopic procedures.

Device Description:

The Compression Anastomosis Clip (CAC) device is a sterile single use device. The CAC provides a simple method for the creation of side-to-side compression anastomosis of the alimentary tract. The CAC device is comprised of two components:

- Clip – double ring clip that is inserted into the two cut segments of the tissue to be anastomosed and performs the required compression on the tissue.

- Applier - with which the Clip is introduced into the treated area.

After a period of 7-10 days, a compression-induced necrosis of the tissue sides underneath the rings occurs and the whole device, together with the necrosed tissue that was compressed by the rings, detaches and is naturally expelled with the stool.

Substantial Equivalence:

Based on validations and performance testing results, including animal studies, NiTi Medical Technologies Ltd. believes that the Compression Anastomosis Clip (CAC) is substantially equivalent to its predicate device cited above 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

SEP 16 2004

Ms. Orly Maor
Regulatory Manger
NiTi Medical Technologies Ltd.
1 Hatzoran St., P.O. Box 8634
Netanya 42506, Israel

Re: K041751
Trade/Device Name: Compression Anastomosis Clip (CAC)
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product Code: FZP
Dated: June 23, 2004
Received: June 29, 2004

Dear Ms. Maor:

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 Office of Compliance at (301) 594-4659. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K041751

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: Compression Anastomosis Clip (CAC)

Indications for Use:

The NiTi CAC is intended to be used to facilitate side-to-side anastomosis of the alimentary tract yielding an inverted serosa-to-serosa anastomosis. Once wound strength is sufficient to maintain the anastomosis, the NiTi CAC is passed from the body. The NiTi CAC is not applicable through Trocars in laparoscopic procedures.

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

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041751