

K030269

Section II: 510(k) Summary

MAR 20 2003

GeniCon, L.C.
Contact: Frank Goldfarb
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Orlando, FL 32878-0038
Telephone: 407 616 3019
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Date Prepared: February 28, 2003

Trade Name: GeniCon Clip Applier
Common Name: GeniCon Clip Applier

Classification Name: According to Section 513 of the Federal Food, Drug, Cosmetic Act, the device classification is Class II, performance Standards (21 CFR 878.4800).

Predicate Device: United States Surgical Corporation

Product Description: The Genicon Clip Applier is a disposable device with a plastic handle and a working shaft that is approximately 32cm in length. Within the shaft are 20 titanium clips. The handle of the instrument is depressed and a titanium clip, which resides in the distal jaw of the instrument, is pressed together around whatever structure is within the jaw of the instrument.

Indications for Use:

The GeniCon Clip applier am implantable clips are intended for use during laparoscopic procedures for the purpose of approximating soft tissue, closing off vessels and other structures in order to stop bleeding or to connect internal tissues to aid in healing.

Performance:

A series of performance tests were performed on the GeniCon Clip Applier to test such areas as:

1. Stress/Exposure Testing
2. Cleaning/Disinfection/Sterilization Testing

The FDA has not adopted performance standards for this product.

Conclusion:

Based on the indications for use, technological characteristics and performance testing, the GeniCon Clip Applier has been shown to be effective for its intended use and substantially equivalent to the predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 20 2003

Mr. Frank Goldfarb
Sales Manager
GeniCon, L.C.
P.O. Box 780038
Orlando, Florida 32878-0038

Re: K030269
Trade/Device Name: Disposable Clip Applier
Regulation Number: 21 CFR 878.4300, 21 CFR 878.4800
Regulation Name: Implantable Clip, Surgical Clip Applier
Regulatory Class: II
Product Code: FZP, GDO
Dated: March 3, 2003
Received: March 6, 2003

Dear Mr. Goldfarb:

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.

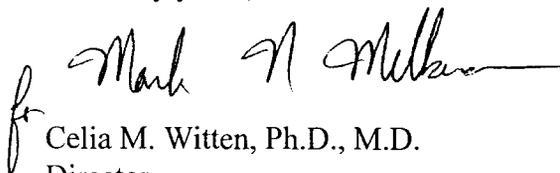
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

Page 2 - Mr. Frank Goldfarb

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. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a long horizontal line extending to the right.

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

510(k): KD30269

Section I. Indications for Use

Page: I-1

Device Name: Disposable Clip Applier

Indications for Use:

The GeniCon Clip Applier and implantable clips are intended for use during laparoscopic procedures for the purpose of approximating soft tissue, closing off vessels and other structures in order to stop bleeding or to connect internal tissues to aid in healing.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Prescription Use _____
Use _____

OR Over-The-Counter

(Optional Format 1-2-96)

for Mark A. Milken

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

510(k) Number K030269