K052241

1.0 510(k) Summary of Safety and Effectiveness

This 510(k) safety and effectiveness summary is being submitted in accordance with the requirements of The Safe Medical Devices Act of 1990 and 21 CFR 807.92.

1.1 Company Name and Address:

Ellman International, Inc.
3333 Royal Avenue
Oceanside, NY 11572
Contact Individual: Joan Carter
Vice President
Jcarter@ellman.com
Tel: (516) 267-6522
Fax: (516) 881-3002

1.2 Device Name: Proprietary Name: Disc-FX™ System
Common / Usual Name Electrosurgical Device and Accessories

1.3 Classification: Electrosurgery Cutting and Coagulation Devices and Accessories (21 CFR 878.4400)

1.4 Device Description:

The Disc-FX™ System is a single-use disposable kit that contains the following disposable components:

1. Trigger-Flex™ Bipolar System
2. Trigger-Flex™ Depth Stop
3. Guidewire
4. Cannula, Straight
5. Cannula, Beveled
6. Cannula Depth Stop
7. Tapered Dilator
8. Trephine

1.5 Intended Use: Disc-FX™ System is intended for use in ablation and coagulation of intrervertebral disc material during discectomy procedures in the lumbar spine.

1.6 Substantial Equivalence

This 510(k) premarket notification is being submitted for the Ellman Disc-FX™ System. The Ellman Disc-FX™ System is substantially equivalent to currently marketed bipolar electrosurgical (RF probes) and spine access (guidewire, cannula, tapered dilator, and trephine) devices as regards intended use (percutaneous access and treatment of intrervertebral disc tissue) , biomechanical performance, and technological characteristics (materials, construction, and mode of operation). A Substantial Equivalence Comparison Chart (Section 4.1) and Predicate Device 510(k) Summaries with Product Brochures are included in Section 4.2.

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1.7 Performance Testing:

Mechanical performance tests were performed for the Ellman Disc-FX™ System to verify the device meets design specifications and intended performance characteristics.

Disc-FX™ components were utilized in multiple discectomy procedures by a doctor skilled in percutaneous and endoscopic spine procedures. A clinical experience summary is provided in Section 5.

Ellman has determined, based upon testing/clinical investigation results that the device conforms to its specifications and is at least as safe and effective as the predicate devices for discectomy procedures.

1.8 Sterilization: A detailed Sterilization Protocol (Section 3.3) and Validation Summary (Section 3.4) are included in this submission which are specific to the Trigger-Flex™ device. As the molded plastic and Stainless Steel components of the Trigger-Flex™ are identical to the materials of other Disc-FX™ components; Guidewire, Cannula's, Tapered Dilator and Trephine, we submit this data for the entire system.

1.9 Other Considerations:

a. Electorosurgical Generator - is not part of this 510K submission. Surgitron Surgi-Max Dual Frequency (K001253) unit is intended for use with Disc-FX™ System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 7 2006

Ellman International, Inc.
c/o Ms. Joan L. Carter
Vice President
3333 Royal Avenue
Oceanside, New York 11572-3625

Re: K052241
Trade/Device Name: Disc-FX™ System
Regulation Number: 21 CFR 888.1100 and 21 CFR 878.4400
Regulation Name: Arthroscope, Elecrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: HRX, GEI
Dated: December 28, 2005
Received: December 29, 2005

Dear Ms. Carter:

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.

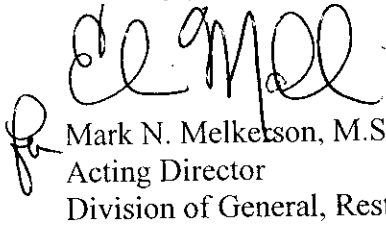
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Sincerely yours,



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

Enclosure

Indications for Use

510(k) Number (if known): K052241

Device Name: Disc-FX™ System

Indications for Use: The Disc-FX™ System is intended for use in ablation and coagulation of intervertebral disc material during discectomy procedures in the lumbar spine.

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 Evaluations (ODE)

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

510(k) Number K052241