K 103840

FEB 28 2011

510(K) SUMMARY K103840
January 7, 2011

SUBMITTER INFORMATION: (2424366)

Flexbar Machine Corp.
d/b/a Mediflex Surgical Products
250 Gibbs Road
Islandia, New York 11749
Tel: 631-582-8440 Fax: 631-582-8487
Contact: Mr. Larry Derrig

APPLICANT/FDA AGENT/CORRESPONDING OFFICIAL INFORMATION:

North American Technical Services (NATS) Corp.
30 Northport Rd
Sound Beach, NY 11789
Tel: 631-744-0059 Fax: 631-744-0192 Email: natscorp@aol.com
Contact: Stephen T. Mlcoch

DEVICE NAME:

Common Name: Disposable Laparoscopic Scissor Tips and reusable Handle
Proprietary Model: Disposable Scissor Tips: 91710, 91720, 91730, 91740, 91750
Handle: The Edge System
Classification: 2
Classification Code: GCJ, 21CFR 876.1500 Laparoscope, General & Plastic Surgery
GEI, 21CFR 878.4400 Electrosurgical, Cutting & Coagulation & Accessories

PREDICATE DEVICE:

Ackermann Instrumente – K974382; Laparoscope Scissor Tips and Handle

DESCRIPTION:

The Laparoscopic Scissor Tips are accessory disposable components that attach to the reusable Laparoscopic Surgical Handle. Laparoscopic Scissor Tips are assembled from medical grade stainless steel and sterilized for single use with the reusable surgical handle that must be cleaned and sterile before use. The Edge System is used with a standard electrosurgical generator and is a monopolar system. The handle is a standard insulated monopolar type with an insulated shaft.

The Laparoscopic Scissor Tips and Handle are substantially equivalent in safety and effectiveness to the legally marketed Scissor Tips and Handle per 510(K) Number K974382. The use, indications and operation are the same for electro and non-electro surgical handles and tips of this type. The 5 tip types identified are for established medical procedures identified as Curved Metzenbaum 91710, Straight Metzenbaum 91720, Mini Metzenbaum 91730, Hook 91740, and Maryland Dissector 91750.

INTENDED USE:

The disposable accessory Laparoscopic Scissor Tips and Handle are used for electrical and non-electrosurgical procedures intended for providing access to and visualization of body cavities, organs and canals to perform various diagnostic and therapeutic surgical procedures.

SUMMARY OF NONCLINICAL TESTS AND DESIGN CONTROL ACTIVITIES:

The Laparoscopic Scissor Tips and Handle comply with the standards below and are therefore safe for the intended use. The device has been tested, validated and has verification procedures in place to confirm design specifications. Compliance with the following mandatory and voluntary standards has been made:

- IEC60601-1, IEC60601-1-2, IEC60601-2-2 are applicable for safety, HF Dielectric and Leakage.

- EN550 Sterilization of Tips by contract sterilizer.

- GMP/ISO13485 Quality System Certification
  Factory procedures are established for production and assembly. Flexbar performs additional QC procedures to confirm design characteristics and performance criteria.

The control activity shows that there are no new questions of safety and effectiveness for the Laparoscopic Scissor Tips and Handle made by Flexbar. The design analysis and predicate comparison confirm the functional characteristics are the same to the predicate device and raise no other safety or effectiveness issues. Inspection verification procedures assure retention of tips, grasping, insulation performance with analyzer and cutting performance are compliant to Flexbar specifications.

CONCLUSION:

The Flexbar Laparoscopic Scissor Tips and Handle are substantially equivalent to the Ackerman Scissor Tips and Handle. They have same intended use and are capable of electrical and non-electrosurgical medical procedure uses.

Note key comparison and equivalence items here:

- Same tip materials.
- Same type handle construction.
- The scissor tips are sterilized and packaged for single use.
- Handle is reusable per product instructions.
- Intended use is the same.

(medi/0033fm)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Flexbar Machine Corp.
% North American Technical Services (NATS) Corp.
Mr. Stephen T. Mlcoch
30 Northport Road
Sound Beach, New York 11789

FEB 28 2011

Re: K103840
Trade/Device Name: Disposable Laparoscopic Scissor Tips and Reusable Handle: The Edge System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 25, 2010
Received: January 04, 2011

Dear Mr. Mlcoch:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K103840

INDICATIONS FOR USE

510K #:	K103840
Device Name:	Accessory Disposable Laparoscopic Scissor Tips and Reuseable Handle, The Edge System
Indications for Use:	The disposable Laparoscopic Scissor Tips and reuseable Handle are used in electrical and non-electrosurgical procedures intended for providing access to and visualization of body cavities, organs and canals to perform various diagnostic and therapeutic surgical procedures.

Prescription Use ___X___ 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)

Neil R. Ogden for mkm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103840