510(K) SUMMARY – K123728
August 29, 2012

DEC 1 1 2013

SUBMITTER INFORMATION: (2424366)

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

FDA AGENT/CORRESPONDING OFFICIAL INFORMATION:

North American Technical Services (NATS) Corp.
30 Northport Rd
Sound Beach, NY 11789
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Contact: Stephen T. Mlcoch

DEVICE NAME:

Name: Laparoscopic Tissue Retrieval Bag, Model 24003-MF
Proprietary Model: 24003-MF
Classification: II
Product Code: GCJ
Regulation: 21 CFR 876.1500

PREDICATE DEVICES:

Vernon-Carus Limited, K033842 Models Nubert, Albert, and Hubert

DESCRIPTION:

The Mediflex device model 24003-MF is for endoscopic retrieval of tissue. It consists of a sterile pouch bag wrapped in coated paper inside a Tyvek peel pouch that is a single use, disposable and durable device. The pouch bag is made of polyurethane coated polyamide. It is suitable for collection and extraction of tissue through 10, 11 or 12mm cannula during laparoscopic surgical procedures. The sterile pouch bag construction is suitable for function and made for opening and closure during the surgical retrieval process. The outer Tyvek peel pouch is marked with the device identification.

SUBSTANCIAL EQUIVALENCE AND TECHNOLOGY:

The Mediflex laparoscopic tissue retrieval bag model 24003-MF is substantially equivalent in design, construction and materials to the identified predicate device model Nubert. They both use the same technology, function the same way and have the identical purpose. They both are the same size and open or close in an identical procedure. There is a Tyvek peel pouch that contains the coated paper over the sterile pouch bag made of polyurethane (PU) coating over nylon polyamide.

The difference to the predicate device is the material source vendor used for the sterile pouch bag but not the material type. Both use the same generic polyurethane (PU) coating over nylon polyamide for the sterile pouch bag. The sterilization methods differ too. EO method is used for 24003-MF and a radiation process is used for predicate model Nubert.

Sterilization by means of EO by the contract sterilizer assures a sterility assurance level of 10^{-6}. The biocompatibility evaluation has shown compliance to ISO10993-1 for the predicate device Nubert and 24003-MF. The specific test evaluations assure material source differences are compliant. Therefore, this device is as safe. It is as effective and performs equivalent to the predicate device by sustaining the same construction. The use of Tyvek peel pouch as a container for the sterile tissue pouch assures a durable and equivalent method to the validated predicate device bag container.

COMPARISON TO PREDICATE DEVICE:

CHARACTERISTICS	FLEXBAR MACHINE CORP d/b/a MEDIFLEX 24003-MF	VERNON-CARUS LIMITED K033842 NUBERT
STERILE	ISO11135-1 EO method (SAL: 10^{-6})	Radiation process (SAL: 10^{-6})
SIZE	Area dimension 195mm x 90mm (see drawing Section 11)	Area dimension 195mm x 90mm
STERILE BAG MATERIAL	PU coated on nylon polyamide	PU coated on nylon polyamide
OPEN / CLOSE METHOD	Instruction 1 page Section 13	Instruction 2 pages Section 12
DISPOSAL	One (1) time use	One (1) time use
FUNCTION	Collection, extraction of tissue via 10mm, 11mm or 12mm cannula	Collection, extraction of tissue via 10mm, 11mm or 12mm cannula
BIOCOMPATIBILITY	ISO10993-1	ISO10993-1
DURABILITY/LIFE	ISO11607 / 5 year shelf Tyvek Peel Pouch	ISO11607 / 5 year shelf
BODY CONTACT TYPE/DURATION	Tissue, Blood / <24 hr	Tissue, Blood / <24 hr

INDICATIONS AND INTENDED USE:

The Mediflex device is a laparoscopic tissue retrieval bag model 24003-MF. The sterile bag is a single use disposable device used as a receptacle for collection and extraction of tissue during laparoscopic surgical procedures.

SUMMARY OF NONCLINICAL TESTS AND DESIGN CONTROL ACTIVITIES:

The performance and safety bench testing activities were conducted on the tissue retrieval bag to establish the safety compliance is sustained for the new device. Validation and verification of compliance with the following mandatory and voluntary standards has been made to validate new production process using new vendor sources are compliant.

- ISO9001/GMP/ISO13485: Quality System Certification
- ISO14971-1:2007 Risk Management

- ISO10993-1:2009 Biocompatibility
- ISO10993-10:1995 Sensitization Test
- ISO10993-10:1995 Irritation / Intracutaneous Reactivity Test
- ISO10993-5:1999 Memelution Cell Culture Cytotoxicity Test
- ISO10993-4:2002 Hemolysis Test
- ISO10993-11:2006 Systemic Toxicity Test
- ISO10993-11:2006 Pyrogenicity Test
- ISO11135-1:2007 Sterilization Validation
- ISO11607-2:2009 Sealing and Accelerated Aging
- ISO11737-1:2006 Bioburden Test
- EN868-5 Annex D Sealing Strength
- ASTM F1929-98 Dye Penetration Test
- EN868-5 Annex E Pealing Characteristic
- EN868-5 Annex B Resistance of Sterilization

Factory and contract vendor locations are qualified. A registered contract sterilizer and quality system certification for the contract factory exists to support Flexbar Machine Corp., manufacturing requirements. The risk analysis shows that there are no new questions of safety and effectiveness for the Mediflex laparoscopic tissue retrieval bag model 24003-MF.

CONCLUSION:

The Mediflex laparoscopic tissue retrieval bag model 24003-MF is substantially equivalent to the predicate device identified. It is suitable for the same use and functions according to equivalent device instructions. The same construction, function, technology exist with equivalent materials. The material source differences are validated by new tests. Differences in sterility methods and containment bag have been validated. There is controlled production activity, test validation history to recognized Standards and production verification procedures in place. No new safety issues are evident and the test evaluation compliance demonstrates the device is as safe, effective and performs as well as the predicate device. Substantial equivalence is evident.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Flexbar Machine Corporation (d/b/a Mediflex)
c/o Stephen T. Mlcoch
North American Technical Services (NATS) Corp.
30 Northport Road
Sound Beach, New York 11789

December 11, 2013

Re: K123728
Trade/Device Name: Laparoscopic Tissue Retrieval Bag, Model 24003-MF
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: September 26, 2013
Received: November 13, 2013

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,

Joshua C. Nipper -S

For Binita Ashar, MD, MBA, FACS
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K123728

INDICATIONS FOR USE

510(K) Number (if known): K123728

Device Name: Laparoscopic Tissue Retrieval Bag model 24003-MF

Indications for Use: The Mediflex device is a laparoscopic tissue retrieval bag model 24003-MF. The sterile bag is a single use disposable device used as a receptacle for collection and extraction of tissue during laparoscopic 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)

Long H. Chen -A

Digitally signed by Long H. Chen -A
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -A, 0.9.2342.19200300.100.1.1=1300369056
Date: 2013.12.10 07:08:04 -05'00'

for BSA

(Division Sign-off)
Division of Surgical Devices
510(k) Number: K123728