CareFusion

SEP 7 2012

510(k) SUMMARY

The following is a summary of 510(k) safety and effectiveness information in accordance with 21 CFR 807.92.

SUBMITTER INFORMATION	
Name	CareFusion 2200 Inc.
Address	1500 Waukegan Road, McGaw Park, IL 60085 USA
Phone Number	847-473-7334
Fax Number	847-473-7790
Establishment Registration Number	1423507
Name of Contact Person	Kate Fuller
Date Prepared	June 22, 2012
NAME OF DEVICE	
Trade or Proprietary Name	Snowden-Pencer™ Laparoscopic Ergonomic Reposable Scissors
Common or Usual Name	Laparoscopic Scissors
Classification Name	Electrosurgical, Cutting & Coagulation and Accessories
Classification Panel	79
Regulation	878.4800
Product Code	GEI, HET
Legally marketed device(s) to which equivalence is claimed	K030890 – Snowden-Pencer Switchblade Scissors K931340 – V. Mueller Laparoscopic Scissors
Reason for 510(k) submission	Modify the take-apart feature on the device from a disposable scissors tip to a disposable shaft and scissors tip.

Device Description

The Snowden-Pencer™ Laparoscopic Ergonomic Reposable Scissors is a monopolar electrosurgical instrument that is intended to produce a specific tissue effect such as dissecting, cutting, or coagulation by directing a variety of electrical high frequency currents through to a target tissue without causing damage to non-target tissue. The scissors are designed to fit

through a 5 mm trocar and are intended to cut, dissect and coagulate tissue during general laparoscopic and gynecological procedures. The device can be used in either the electrified or non-electrified state.

The device has a disposable shaft and scissors tip (scissors insert) and a reusable handle. The scissors are available in three lengths 24, 36 and 45 cm and three blade designs: curved metzenbaum, mini-metzenbaum and hook.

The disposable scissors insert is provided sterile and is for single use only. The handle can be reused following cleaning and sterilization and is supplied non sterile.

Indications for Use

The Snowden-Pencer Laparoscopic Ergonomic Reposable Scissors is a monopolar electrosurgical instrument indicated to be used in general laparoscopic and gynecologic procedures to allow high frequency monopolar cutting and coagulation. The reposable scissors are indicated to mechanically cut tissue and suture.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICES.

Characteristic	Modified Device	Switchblade Scissors K030890 (Predicate)	V. Mueller Laparoscopic Scissors K931340 (Predicate)
Reposable Device	Reusable Handle/Disposable Shaft and Scissors Tip	Reusable Handle and Shaft/Disposable Scissors Tip	Reusable Handle and Shaft/Disposable Scissors Tip
Insulation	MT5000 Polyolefin	Polyvinylidene Fluoride (PVDF) Kynar	Ptfe Teflon
Blade Designs	Metz, Mini Metz, Hook	SAME	SAME
Electrical Rating	1kVp	0.5kVp	Not Specified
Sterilization – Handle	Pre-Vacuum Steam (Wrapped)	SAME	SAME
Sterilization – Tip	EtO	Same	Gamma

The modified single-use disposable scissors tips and shaft is identical in intended use, principle of operations, and energy type to both the Switchblade Scissors and the V. Mueller® Laparoscopic Scissors. These devices provide delivery of high frequency energy through a connection to a monopolar electrical generator with a universal high frequency monopolar electrosurgical cord.

The modified device, like the predicates, is intended to cut and coagulate and can be used in either an electrified or non electrified state. The modified product has the same basic scissors tip design and is comprised of medical grade stainless steel. The modified device works in the same manner as the predicates, is of similar lengths, and is designed to be used through a 5 mm trocar. The insulation of the modified device has been used in other currently marketed HF surgical devices and has been tested for safety and effectiveness when used with HF monopolar energy.

The modified design has a disposable scissors tip and shaft, simplifying the cleaning of the

handle by designing the device so that both the tip and the shaft are disposed after a single use.

All materials used in the construction of the modified device have been tested for safety and effectiveness and are deemed to be substantially equivalent to the predicate devices.

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Performance Test Summary – Modified Device

Characteristic	Standard/Test/FDA Guidance	Testing Conclusions
Electrosurgical Safety and Performance Tests	IEC 60601-1, 60601-2, 60601-2-2, 60601-2-18	All three scissors tips designs passed the $1kV_p$ High Frequency Test and the Mains Frequency Test.
Cut and Coagulation Performance Tests	Bench top and design validation testing	All three scissors tip designs, as appropriate, successfully cut a variety of material (tissue, suture, and gastric band). Scissors successfully dissect during electrosurgical cutting and coagulation.
Biocompatibility Tests	ISO 10993-1, 10993-5 and 10993-10	Scissors materials are toxicologically and chemically acceptable for the indicated use.
Cleaning and Sterilization Validations	ISO 11135, ISO 11138-1, ISO 11737-1, ISO 11737-2, ISO17664, ISO17665-1, TIR12, ST79, ST81	Validations confirmed a sterility assurance level of 10^{-6}.

SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR CLINICAL INFORMATION

N/A – No clinical tests were conducted for this submission.

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

SEP 7 2012

Carefusion 2200, Incorporated
% Ms. Katherine M. Fuller
Manager, Regulatory Affairs
1500 Waukegan Road
McGaw Park, Illinois 60085

Re: K113407
Trade/Device Name: Snowden-Pencer Laparoscopic Ergonomic Reposable Scissors
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI, HET
Dated: August 24, 2012
Received: August 27, 2012

Dear Ms. Fuller:

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

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510(k) Number: K113407

Device Name: Snowden-Pencer Laparoscopic Ergonomic Reposable Scissors

Indications for Use: The Snowden-Pencer Laparoscopic Ergonomic Reposable Scissors is a monopolar electrosurgical instrument indicated to be used in general laparoscopic and gynecologic procedures to allow high frequency monopolar cutting and coagulation. The reposable scissors are indicated to mechanically cut tissue and suture.

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)

Concurrance of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113407