



Food and Drug Administration
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February 1, 2016

CareFusion 2200 Incorporated
Ms. Jane Weber, MS
Regulatory Affairs Manager
75 North Fairway Drive
Vernon Hills, Illinois 60061

Re: K151036

Trade/Device Name: Snowden-Pencer Ergonomic Take-Apart In-Line
and Pistol-Grip Laparoscopic Instruments

Regulation Number: 21 CFR 876.1500

Regulation Name: Endoscope and accessories

Regulatory Class: Class II

Product Code: GCJ

Dated: December 14, 2015

Received: December 15, 2015

Dear Ms. Weber:

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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151036

Device Name

Snowden-Pencer Ergonomic Take-Apart In-Line and Pistol-Grip Laparoscopic Instruments

Indications for Use (Describe)

Snowden-Pencer Ergonomic Take-Apart In-Line and Pistol-Grip Laparoscopic Instruments are designed to transmit cutting, clamping, grasping, suturing and dissecting force to working tips in minimally invasive surgeries such as plastic and general laparoscopic procedures.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY – K151036



A summary of 510(k) safety and effectiveness information in accordance with 21 CFR 807.92.

SUBMITTER INFORMATION	
Name	CareFusion 2200 Inc
Address	75 N. Fairway Dr. Vernon Hills, IL 60061
Phone number	(847) 362-8094 (Jane Weber)
Fax number	(312) 949-0272 (Jane Weber)
Establishment Registration Number	1423507
Name of contact person	Jane Weber, MS, Regulatory Affairs Manager jane.weber@carefusion.com
Date prepared	27-JAN-2016
DEVICE INFORMATION	
Trade or proprietary name	Snowden-Pencer Ergonomic Take-Apart In-Line and Pistol-Grip Laparoscopic Instruments
Common or usual name	Reusable Laparoscopic Instruments
Classification name	Endoscopic and Accessories
Classification panel	78 Gastroenterology and Urology
Regulation	Class II per 21CFR 876.1500, Product code GCJ
Product Code(s)	Multiple devices
Legally marketed device(s) to which equivalence is claimed	Snowden-Pencer Inc. – Reusable Laparoscopic Instruments – K930667, GCJ
Reason for 510(k) submission	Design modification to allow device to be taken apart
Device description	Snowden-Pencer Ergonomic Take-Apart In-Line and Pistol-Grip Laparoscopic Instruments consists of a handle, shaft and insert. The insert contains an end-effector (jaw pattern). There are several device models that encompass various lengths, diameters and jaw patterns based on the surgeon’s needs.
Intended use of the device	Cutting, clamping, grasping, suturing and dissecting
Indications for use	Snowden-Pencer Ergonomic Take-Apart In-Line and Pistol-Grip Laparoscopic Instruments are designed to transmit cutting, clamping, grasping, suturing and dissecting force to working tips in minimally invasive surgeries such as plastic and general laparoscopic procedures.

510(k) SUMMARY – K151036

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE		
Characteristic	Predicate Device	New Device
Type of Device	Reusable	Reusable
Intended for direct patient contact?	Yes	Yes
Intended for extended use? (more than 24 hrs)	No	No
Cleaning Method	Manual and Automatic	Manual and Automatic
Sterilization Method	Product is sold non-sterile and sterilized by the end user via the following steam sterilization options: <ul style="list-style-type: none"> • Gravity Displacement • Prevacuum 	Product is sold non-sterile and sterilized by the end user via the following steam sterilization options: <ul style="list-style-type: none"> • Prevacuum
Materials	Stainless Steel Aluminum Radel-R Halar Tungsten Carbide	Stainless Steel Radel-R Halar Tungsten Carbide
Handle Configuration	Ring Handle, In-Line handle, and Pistol Grip (bent)	In-Line handle and Pistol Grip (bent)
Shaft/End Effector Rotation Capability	Rotatable and Non Rotatable	Rotatable and Non Rotatable
Instrument Length	24cm, 33cm, 36cm, 45cm	24cm, 33cm, 36cm, 45cm
Instrument Diameter	3.5mm, 5mm, 10mm	5mm and 10mm
End Effectors (Jaw Patterns)	Scissors, Graspers, Dissectors, Clamps and Needle Holders	Scissors, Graspers, Dissectors, Clamps and Needle Holders
Device Configuration	Single-piece design	Take-Apart design

510(k) SUMMARY – K151036

PERFORMANCE DATA		
SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE		
Performance Test Summary - New Device		
Characteristic	Standard / Test / FDA Guidance	Results Summary
Instrument strength	Strength Tests	PASS
Inadvertent disassembly	Pull Strength Test	PASS
Ease of disassembly/reassembly	Force Tests	PASS
Handle must be reusable	Reliability Test	PASS
Handle compatibility with existing shafts and inserts	Handle ability to connect to worst case shafts and inserts	PASS
Device is able to be cleaned and sterilized	AAMI TIR12, AAMI TIR30, ANSI AAMI ST79, ANSI AAMI ST81, ISO 11138, ISO 17664, ISO 17665	PASS
Device materials are biocompatible	ISO 10993	PASS
SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION		
N/A – No clinical tests were conducted for this submission.		
CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA		
The results of the non-clinical tests demonstrate the Snowden-Pencer Ergonomic Take-Apart In-Line and Pistol-Grip Laparoscopic Instruments meet all performance requirements, and are substantially equivalent to the predicate devices.		