DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

May 4, 2017

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

Re: K163615
Trade/Device Name: Snowden-Pencer MicroLap 3mm Laparoscopic Instruments
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 28, 2017
Received: May 2, 2017

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" (21 CFR 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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K163615

Device Name
Snowden-Pencer MicroLap 3mm Laparoscopic Instruments

Indications for Use *(Describe)*
The Snowden-Pencer MicroLap 3mm Laparoscopic Instruments are indicated to be used in laparoscopic and other minimally invasive procedures for cutting, clamping, grasping, suturing and dissecting and to allow high frequency monopolar cutting and coagulation.

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)*

CareFusion
has joined BD

510(k) SUMMARY – K163615

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

SUBMITTER INFORMATION	
Name	CareFusion 2200 Inc.
Address	75 North Fairway Drive Vernon Hills, IL 60061
Phone number	(847) 362-8094
Fax number	(312) 949-0272
Establishment Registration Number	1423507
Name of contact person	Jane Weber
Date prepared	28-APR-2016
DEVICE INFORMATION	
Trade or proprietary name	Snowden-Pencer MicroLap 3mm Laparoscopic Instruments
Common or usual name	Reusable Laparoscopic Instruments
Classification name	Electrosurgical Cutting and Coagulation and Accessories
Classification panel	79 General and Plastic Surgery
Regulation	Class II per 21CFR 878.4400, Product code GEI
Product Code(s)	Multiple devices
Legally marketed device(s) to which equivalence is claimed	BEMA Endoscopic Monopolar Instruments and Accessories – K102921, GEI
Reason for 510(k) submission	Launch new 3mm product line
Device description	Snowden-Pencer MicroLap 3mm Laparoscopic Instruments consists of a handle and insert assembly. The insert assembly contains a shaft and 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	To be used in laparoscopic and other minimally invasive procedures
Indications for use	The Snowden-Pencer MicroLap 3mm Laparoscopic Instruments are indicated to be used in laparoscopic and other minimally invasive procedures for cutting, clamping, grasping, suturing and dissecting and to allow high frequency monopolar cutting and coagulation.

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
Active component	Monopolar	Monopolar
Length	18cm, 21cm, 33cm	24cm and 36cm
Diameter	3mm	3mm
Overall device design	Two-Piece Modular System	Two-Piece Modular System
Handle design	Ring and In-Line	Ring, Pistol-Grip and In-Line
Insert Assembly End Effectors (jaw patterns)	Scissors Graspers Dissectors Needle Holders	Scissors Clamps Graspers Dissectors Needle Holders
Rated Voltage	2 kVp in cutting/coagulation 3 kVp in spray	1.5 kVp in all modes
Materials	Stainless Steel (SS) Raydel (Poylphenlsufone – PPSU) Tungsten Carbide Silver Braze 3M DP490 Halar S Nylon	Stainless Steel Radel (Poylphenlsufone – PPSU) Tungsten Carbide Silver braze 3M DP490 Marabu Tampapur TPU 970 – White Loctite Santoprene EPDM Rubber Kraton
How Supplied	Non-Sterile	Non-Sterile
Sterilization Modalities	Pre-vacuum Steam	Pre-Vacuum Steam

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
Device must be reusable	Cleaning and Sterilization Tests	PASS
Device must maintain pneumoperitoneum	Pneumoperitoneum Test	PASS
Device to meet required electrosurgical safety standards	IEC 60601-1, IEC 60601-2, IEC 60601-2-2, IEC 60601-2-18	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 MicroLap 3mm Laparoscopic Instruments meet all performance requirements, and are substantially equivalent to the predicate devices.		