CareFusion

K110257 p&1 of 3

MAY - 6 2011

510(k) SUMMARY

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

SUBMITTER INFORMATION	
Name	CareFusion Corporation
Address	1500 Waukegan Road MPWM, McGaw Park, IL 60085 USA
Phone number	(847) 473-7429
Fax number	(847) 473-7774
Establishment Registration Number	1423507
Name of contact person	Jane Weber
Date prepared	01/19/2011
DEVICE INFORMATION	
Trade or proprietary name	Diamond-Flex® Graspers and Dissectors
Common or usual name	Reusable Laparoscopic Instrument
Classification name	Endoscope and Accessories
Classification panel	78 Gastroenterology and Urology
Regulation	Class II per 21CFR 876.1500, Product code GCJ
Product Code(s)	89-0500, 89-0501, 89-0502, 89-0503, 89-0504, 89-0505, 89-0506, 89-0507, 89-0508, 89-0509, 89-0510, 89-0511, 89-4500, 89-4501, 89-4502, 89-4503, 89-4504, 89-4505, 89-4506, 89-4507, 89-4508, 89-4509, 89-4510, 89-4511
Legally marketed device(s) to which equivalence is claimed	Snowden-Pencer Inc. - Reusable Laparoscopic Instruments – K930667, GCJ Surgical Innovations Limited – EndoFlex 5000 Endoscopic Forceps – K946239, GCJ
Reason for 510(k) submission	New Device
Device description	Each Diamond-Flex® Grasper and Dissector is comprised of a handle assembly, an elongate shaft and a 'distal end' which comprises a segmented flexible portion and the end-effector or jaw pattern.
Intended use of the device	To grasp and dissect
Indications for use	Diamond-Flex® Graspers and Dissectors are designed to transmit grasping force through delicate working tips in both minimally invasive and open surgical procedures.

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K110257 pg 2 of 3

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE			
Characteristic	**Predicate Device Snowden-Pencer Inc. Reusable Laparoscopic Instruments – K930667**	**Predicate Device Surgical Innovations Limited EndoFlex 5000 Endoscopic Forceps – K946239**	**New Device**
Type of Device	Reusable	Reusable	Reusable
Materials	Stainless Steel	Stainless Steel Nitinol Alloy Santoprene Nylon PEEK Aluminum Tungsten Carbide	Stainless Steel Nitinol Alloy Santoprene Nylon PEEK Aluminum Tungsten Carbide
Length	24cm, 33cm, 45 cm	33cm, 25.5cm	34cm, 45cm
Articulating component	None	Segmented flexible portion that articulates to 40° or 90°	Segmented flexible portion that articulates to 40° or 90°
Articulation mechanism	None	Rotating Actuation knob to tighten cable and form shape	Rotating Actuation knob to tighten cable and form shape
Actuation mechanism	Handle operation causes opening and closing of end effector	Handle operation causes opening and closing of end effector	Handle operation causes opening and closing of end effector
Flush port?	Yes	Yes	Yes
Sterilization sleeve?	No	Yes	Yes
Requires insertion through trocar?	Yes	Yes	Yes
Form inserted into trocar	Not Applicable	Relaxed-unarticulated	Relaxed-unarticulated
Grasper patterns	6	10	6 (same as K930667)

CareFusion K110257 Pg 3 of 3

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**
Maintains pneumoperitoneum	Pneumo-peritoneum Test	PASS
Articulation system strength	Shape Forming Verification Test	PASS
Actuation system strength	Crimp Strength Test	PASS
Instrument to withstand repeated uses	Repeated Simulated Use Test	PASS
Instrument to meet customer needs for grasping, dissecting, and providing sufficient rigidity to the user in the actuated state	Customer Evaluation Report	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 Diamond-Flex® Graspers meet or exceed all performance requirements, and are substantially equivalent to the predicate devices.		

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

MAY - 6 2011

CareFusion 2200, Inc.
% Ms. Jane Weber
Regulatory Affairs Manager
1500 Waukegan Road
McGaw Park, Illinois 60085

Re: K110257
Trade/Device Name: Diamond-Flex® Graspers and Dissectors
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: April 18, 2011
Received: April 20, 2011

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 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

CareFusion

1500 Waukegan Road
McGaw Park, Illinois 60085-6787
847.473.1500
FAX: 847.473.7774

Indications for Use

510(k) Number (if known):

Device Name: Diamond-Flex® Graspers and Dissectors

Indications for Use:

Diamond-Flex® Graspers and Dissectors are designed to transmit grasping force through delicate working tips in both minimally invasive and open surgical procedures.

Prescription Use _X_ or Over-The Counter Use _____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE)

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 K110257