K120518

MAY - 4 2012

Summary of Safety and Effectiveness

The Summary of 510(k) safety and effectiveness is in accordance with 21 CFR 807.92.

SUBMITTER INFORMATION	
Name	CareFusion
Address	1500 Waukegan Road MPWM, McGaw Park, IL 60085 USA
Phone number	(847) 473-7208
Fax number	(847) 473-7774
Establishment Registration Number	8030673
Name of contact person	Erika Fernandez
Date prepared	February 20, 2012

NAME OF DEVICE	
Trade or proprietary name	$ETCO_2$ Nasal Cannula
Common or usual name	Oxygen Delivery, CO_2 Sampling Cannula
Classification name	Carbon Dioxide Gas Analyzer
Classification panel	73 Anesthesiology
Regulation	Class II per 21CFR §868.1400
Product Code(s)	CCK
Legally marketed device(s) to which equivalence is claimed	K863883: Models 4002/4102/4202 Oxy. Delivery/CO_2 Cannula K892406: Modified oxygen delivery/CO_2 Sample Nasal Cannula
Device description	The proposed devices consist of a bifurcated nasal prong with two separate gas conduits. One side of the divided cannula is connected to a gas source for delivering low flow oxygen through flexible tubing to the patient. The other side of the divided cannula directs exhaled gas through flexible tubing to a carbon dioxide monitoring device
Intended use	The $ETCO_2$ Nasal Cannula is an adjunct to oxygen therapy with its primary function being that of delivering low flow oxygen, up to 4 L/min, to a patient while providing a means to sample expired gas. The target population is adult and pediatric patients.
CATALOG NUMBER /MODEL NUMBERS AND DESCRIPTION	
2802M-10	Pediatric with 7' O_2 tube and 7' CO_2 tube with male luer connector
2802F-10	Pediatric with 7' O_2 tube and 7' CO_2 tube with female luer connector
2811M-10	Adult with 7' O_2 tube and 2" CO_2 tube with male luer connector
2811F-10	Adult with 7' O_2 tube and 2" CO_2 tube with female luer connector
2812M-10	Adult with 7' O_2 and 7' CO_2 tube with male luer connector
2812F-10	Adult with 7' O_2 and 7' CO_2 tube with female luer connector
28M2M	$ETCO_2$ Sample Line10' Tube, Male/Male Connectors
28M2F	$ETCO_2$ Sample Line10' Tube, Male/Female Connectors

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE		
Characteristic	**Predicate**	**New Device**
Design	Divided Cannula	Same
	Salter Eyes® (Side holes) in adult prongs	No Salter Eyes® (Side holes) in adult prongs
	7' smooth O_2 & 7' smooth CO_2 paired tubing or	Same
	7' crush resistant O_2 tube & 2" smooth CO_2 tube	Same
	Male or female luer connector	Same
	10'Sample line with male and female connectors	Same
	22mm x 6mm connector	Same
	Universal O_2 connector	Same
Material		
Cannula; adult & pediatric	Flexible PVC	Same
All Tubing; 7' crush resistant & smooth, 10' & 2" smooth	Flexible PVC	Same
Sliding component (lariat)	Polyolefin	Similar
Luer Lock Connector, Male	Rigid thermoplastic	Similar
Luer Lock Connector, Female	Rigid thermoplastic	Similar
Tubing Connector (Y)	Flexible PVC	Similar
Universal Connector (Vinyl tip)	Flexible PVC	Similar
22mm x 6mm connector	Polyolefin	Similar
Sterilization	Non sterile, single use	Same
Packaging configuration	Individually packaged in heat-sealed poly bag with product insert that includes the Instructions for Use. 10 units per shipping carton.	Individually packaged in tape-sealed poly bag with product insert that includes the Instructions for Use. 10 units per shipping carton.

PERFORMANCE DATA

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

Performance Test Summary

Characteristic	Standard/Test/FDA Guidance
Biocompatibility	ISO 10993-1:2009 Biological evaluation of Medical Devices Part 1: Evaluation and Testing
Performance	ISO 594-1 Conical fitting with 6% (Luer) taper for syringes, needles and certain other medical equipment: Part 1- General Requirements
Performance	ISO 594-2 Conical fitting with 6% (Luer) taper for syringes, needles and certain other medical equipment: Part 2- Lock Fittings
Performance	BS EN 13544-2:2002 + A1:2009 Respiratory Therapy Equipment – Part 2: Tubing and Connectors
Performance	ANSI/ISO 5356-1:2004 (MOD) Anesthetic and respiratory equipment - conical connectors – Part 1: Cones and Sockets
Performance	ISO 14971:2009 Medical devices — Application of Risk Management to Medical Devices
Performance	Gas Flow Bench Testing (O_2 Delivery Line) Maximum Flow Resistance: 138 mmH_2O per foot @ 4 lpm, Pediatric Maximum Flow Resistance: 119 mmH_2O per foot @ 4 lpm, Adult
Performance	Gas Flow Bench Testing (CO_2 Cannula Sampling Line) Maximum Flow Resistance: 51 mmH_2O per foot @ 0.5 lpm, Pediatric Maximum Flow Resistance: 65 mmH_2O per foot @ 0.5 lpm, Adult
Performance	Gas Flow Bench Testing (CO_2 Sampling Line) Maximum Flow Resistance: 64 mmH_2O per foot @ 0.5 lpm

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 show that the $ETCO_2$ Nasal Cannula meets all performance requirements, and is 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

Ms. Erika Fernandez
Regulatory Affairs Manager
CareFusion
1500 Waukegan Road
Waukegan, Illinois 60085

MAY - 4 2012

Re: K120518
Trade/Device Name: End-Tidal CO2 Nasal Cannula
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Das Analyzer
Regulatory Class: II
Product Code: CCK
Dated: April 3, 2012
Received: April 5, 2012

Dear Ms. Fernandez:

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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1500 Waukegan Road
McGaw Park, Illinois 60085
phone: 847.473.1500

carefusion.com

CareFusion

Indication for Use

510(k) Number (if known): Unknown at this time

Device Name: End-Tidal CO_2 Nasal Cannula

Indications for Use: *The $ETCO_2$ Nasal Cannula is an adjunct to oxygen therapy with its primary function being that of delivering low flow oxygen, up to 4 L/min, to a patient while providing a means to sample expired gas. The target population is adult and pediatric patients.*

Prescription Use _X__ or Over-The Counter Use _____

(Per 21 CFR 801 Subpart D) (Per 21 CFR 870 Subpart C)

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

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120519