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510(k) Summary

Trade name	O2 Nasal cannula with CO2 monitorin
C.F.R Section Product Code:	21 CFR 868.1400. Carbon Dioxide ga CCK
Manufacturer:	Flexicare Medical Limited Cynon Valley Business Park Mountain Ash, Mid. Glam. CF45 4ER. United Kingdom
Regulatory Affairs Contact:	Christopher Watkins Quality Regulatory & Technical Direct Flexicare Medical Limited Cynon Valley Business Park Mountain Ash, Mid. Glam. CF45 4ER. United Kingdom
Telephone:	00 44 1443 471 593
Date Summary Prepared:	March 2014
Common Name:	Nasal cannula with CO2 monitoring
Classification:	Class 2
Predicate Device	Unomedical - Mac-Safe (was Hospita sampling/oxygen delivery cannula") w marketing by 510(k) No K915228.
Description:	O2 Nasal cannula with CO2 monitorin that is intended to situate under the pa prongs of the cannula inserted into pa oxygen is administered and CO2 mon The O2 Nasal cannula with CO2 mon administering prongs, tube slide, co-e

The O2 Nasal cannula with CO2 mon
extruded tubes

Part Numbers:

	Nasal cannula with CO2 monitoring
020-10-123U	O2 NASAL CANNULA WITH CO2 MONITORING – ADULT - MALE PIGT
020-10-124U	O2 NASAL CANNULA WITH CO2 MONITORING – ADULT - FEMALE PI
020-10-125U	O2 NASAL CANNULA WITH CO2 MONITORING – ADULT - MALE LUE
020-10-125AU	O2 NASAL CANNULA WITH CO2 MONITORING – ADULT - MALE LUE
020-10-126U	O2 NASAL CANNULA WITH CO2 MONITORING – ADULT - FEMALE LU
020-10-126AU	O2 NASAL CANNULA WITH CO2 MONITORING – ADULT - FEMALE LU
020-10-127U	O2 NASAL CANNULA WITH CO2 MONITORING – ADULT - MALE LUEF
020-10-128U	O2 NASAL CANNULA WITH CO2 MONITORING – ADULT - FEMALE LU

Intended Use:

O2 Nasal cannula with CO2 monitoring is
patients who require supplemental oxyge
monitoring

Substantial Equivalence

O2 Nasal cannula with CO2 monitorin
use as predicate device:

- Unomedical - Mac-Safe (was Hospital
sampling/oxygen delivery cannula") w
marketing by 510(k) No K915228.

Both O2 delivering/CO2 monitoring de
use devices.
Neither device is life supporting or life

Neither device uses software/ and are

Both O2 delivering/CO2 monitoring de
sterile in individual poly bags.

Both O2 delivering/CO2 monitoring de

	FlexicareO2 Nasal cannula with CO2 monitoring K: Unknown	Unomedical - Ma CO2 gas sampling was cl
Conforms to: BS EN 13544-2: 2002 +A1:2009 Annex A4 And BS EN 13544-2: 2002 +A1:2009 Annex A5	Yes	
Components	Co extruded O2/CO2 tubing luer connector (male/female) Cannula delivery/cannula prongs O2 Connector Tube slide Y-piece Venturi barrel Hydrophilic filter (option)	Co ex luer c Cannula
Materials	PVC Polypropylene ABS	
Assembly method	Bonded – Solvent adhesive	Bond
Target population	Adult	
Home use	No	
Hospital/ emergency use	Yes	
Connectable to Capnograph?	Yes	
Monitors CO2?	Yes	

Colour/ size/ material	Devices displayed a high level of substantial equivalence. All within 0.1mm of each other. ID's are classed as critical dim resistance/rate through tubi All materials are the same, with any differences being mini e.g. colour/finish.	
ID/ OD/ length O2 tubing CO2 tubing	ID: 3.9mm OD: 5.0mm Length: 2100mm ID: 1.4 OD: 2.7 Length: 2100mm	

Tests Performed:

Test	Standard? / In-House?
Visual inspection	In-House
Nipple dimensions (on venturi barrel supplied with cannula)	BS EN13544-2: 2002 +A1:2009 Annex A5
Strength of nipple(on venturi barrel supplied with cannula)	
Tubing flow resistance	
O2 Connector to tubing tensile strength	
O2 Connector to nipple tensile strength	
Tube resistance to kinking	
Dimensional inspection of luer conical	ISO 594-1 / BS EN 20594-1:1994.
Dimensional inspection of luer conical	ISO 594-2 (BS EN 1707:1997)
Gauging tests on luer	
Liquid leakage from luer	
Air leakage from luer	
Luer separation force	
Luer unscrewing torque	

All Samples passed the performance testing when tested against methods
House test methods and relevant BS EN standards.

The results of this testing show that the O2 Nasal cannula with CO2 monit
performance tests and performs at least as well as marketed predicate dev
Unomedical.

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

March 6, 2014

Flexicare Medical Limited
C/O Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25TH Street NW
Buffalo, MN 55313

Re: K140113
Trade/Device Name: O2 Nasal Cannula with CO2 Monitoring
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: II
Product Code: CCK
Dated: February 18, 2014
Received: February 21, 2014

Dear Mr. Job:

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.

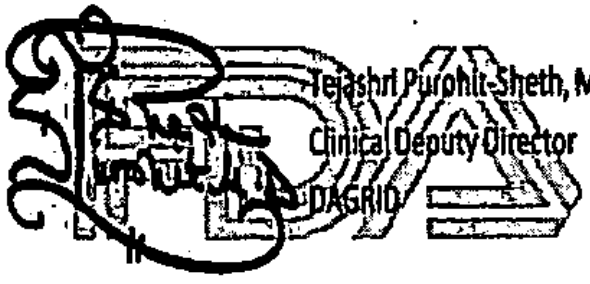
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determ
that FDA has made a determination that your device complies with other
or any Federal statutes and regulations administered by other Federal ager
comply with all the Act's requirements, including, but not limited to: regi
CFR Part 807); labeling (21 CFR Part 801); medical device reporting (rep
device-related adverse events) (21 CFR 803); good manufacturing practic
forth in the quality systems (QS) regulation (21 CFR Part 820); and if app
product radiation control provisions (Sections 531-542 of the Act); 21 CF

If you desire specific advice for your device on our labeling regulation (2
contact the Division of Small Manufacturers, International and Consumer
free number (800) 638-2041 or (301) 796-7100 or at its Internet address
http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.ht
the regulation entitled, "Misbranding by reference to premarket notificati
807.97). For questions regarding the reporting of adverse events under th
CFR Part 803), please go to
http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm
of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under
Division of Small Manufacturers, International and Consumer Assistance
(800) 638-2041 or (301) 796-7100 or at its Internet address
http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.ht

Sincerely yours,



Erin I. Keith, M.S.
Acting Director

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)*
K140113

Device Name
O2 Nasal Cannula with CO2 monitoring

Indications for Use *(Describe)*

O2 Nasal Cannula with CO2 monitoring is intended for use in Adult patients who require supplemental oxygen delivery and CO2 monitoring

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)*

Todd D. Courtney -S
2014.03.06 16:00:49 -05'00'