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APR 1 0 2014

K140473

510(k) Summary

510(k) Sponsor, Contact Person and Date Summary Prepared:

Flexicare Medical Limited
Cynon Valley Business Park
Mountain Ash, Mid. Glamorgan
CF45 4ER. United Kingdom

Christopher Watkins
Quality Regulatory & Technical Director
Telephone: 00 44 1443 471 593
Fax: 00 44 1443 474 222

Summary prepared on: 10th April 2014

Device Name:

Trade Name: DualGuard™
Common/Usual Name: Endoscopic bite block and nasal oxygen cannula with CO2 monitoring accessory

Classification Name: Primary Classification: Carbon dioxide analyzer 21 CFR 868.1400
Primary Product Code: CCK
Secondary Product Codes:
Endoscopic bite block (MNK), Nasal oxygen cannula (CAT)

Legally Marketed Equivalent Device:

The DualGuard™ is substantially equivalent to Trawax's TwinGuard® cleared under 510(k) K080527.

Device Description:

DualGuard™ is an endoscopic bite block which is designed to fit into the nose and mouth of the patient during an endoscopy procedure.

DualGuard™ consists of a bite block with a removable oxygen delivering/ CO2 monitoring cannula, which when attached located under the patient nose. The bite block also has an Oral CO2 monitoring line attached at the mouth opening. DualGuard™ is able to deliver oxygen via the nose, whilst sampling CO2 from the nose and mouth.

When the Endoscopy is complete the bite block of DualGuard™ can be removed whilst leaving the cannula in place on patient, delivering oxygen and monitoring CO2.

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DualGuard™ has a soft TPE over molded Bite block to reduce the risk of damage to teeth, a tube slide for securing, and an adjustable head strap for a secure comfortable fit.

The CO2 line from the DualGuard™ has a self sealing "luersafe" luer port which allows the oral CO2 line to be removed with the bite block without any leaking of CO2 or ingress of air that may cause an inaccurate reading.

DualGuard™ is available in adult size only.

Intended Use:

DualGuard™ is intended for use in Adult patients who require supplemental oxygen delivery and CO2 monitoring during endoscopy procedures and recovery.
The complete device with bite block is to be used during endoscopy procedures.
The DualGuard™ Bite Block is to be removed after endoscopy, leaving the O2 delivering/CO2 sampling cannula in place for patient recovery period.

Substantial Equivalence:

DualGuard™ has the same intended use as the predicate device.
Both the DualGuard and TwinGuard are single patient use devices. Supplied in Adult size only.
Neither device is life supporting or life sustaining.

Patient Contact –
Bite block - Invasive – Mucosal membrane – Limited duration (>24hrs)
Cannula & tubing – skin contact (intact) and externally communicating – Limited duration (>24hrs)

Neither the DualGuard nor the TwinGuard uses software/ neither are electronically driven.
Both devices are supplied non-sterile in individual poly bags.

Both devices are able to be used with industry standard devices such as oxygen cylinders/connectors and Capnograph machines.

Both the DualGuard and TwinGuard devices are designed for the same intended use in the same intended conditions.
Both designs consist of 10+ components made from injection molded & extruded plastics.

From comparison testing it was determined that the only invasive components of the two devices were the bite blocks.
The DualGuard bite blocks are manufactured from Polypropylene with a soft TPE section over molded.
TwinGuard bite blocks are also manufactured from Polypropylene but do not have an over molded section.

The Oxygen tubing, cannula, CO2 line and oxygen connector of both the DualGuard and TwinGuard devices are manufactured from PVC.
The Trawax "TwinGuard" bite block is Green in color with clear tubing. The Flexicare DualGuard™ is Blue & orange in color with clear tubing. This difference in color is by

manufacturer's choice/ branding, and is not related to sizing, intended use, gender of patient or performance of device.
Both the DualGuard and Predicate devices have 2M oxygen & CO2 lines.

	Flexicare DualGuard™ K: Unknown	Trawax "TwinGuard" K080527
Components	O2 tube O2 connector CO2 line CO2 luer Bite block TPE over mold Nasal cannula Head strap Tube slide Oral CO2 tube link Self sealing CO2 Y-piece Oral CO2 luer 0.45µm Hydrophobic filter	O2 tube O2 connector CO2 line CO2 luer Bite block Nasal cannula Head strap Tube slide Oral CO2 tube link
Materials	Medical grade PVC Medical grade Polypropylene Medical grade ABS Medical grade TPE Medical grade ABS/Nylon (filter)	Medical grade PVC Medical grade Polypropylene Medical grade ABS
Target population	Adult	Adult
Home use	No	No
Emergency use	Yes	Yes
Assembly method	Bonded – Solvent adhesive	Bonded – Solvent adhesive
Connectable to Capnograph?	Yes	Yes
Monitors CO2?	Yes	Yes
Nasal CO2 monitoring?	Yes	Yes
Oral CO2 monitoring?	Yes	Yes
Use	Single use	Single use
Supplied sterile	No	No
Soft molded bite area?	Yes	No

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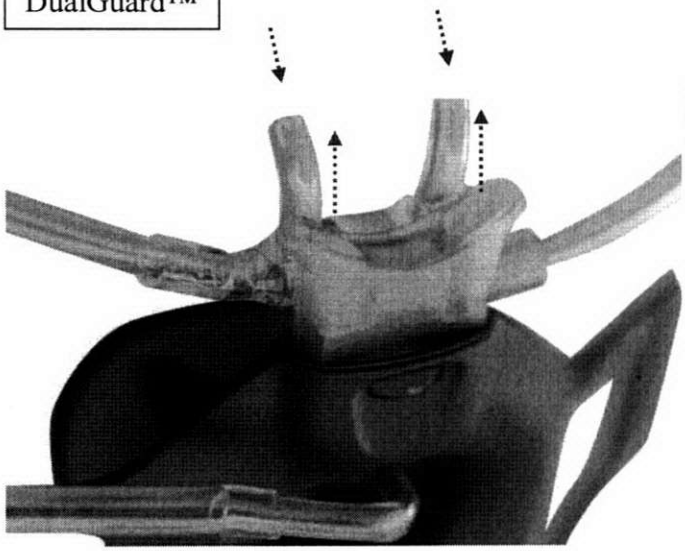
Indications for use	DualGuard™ is intended for use in Adult patients who require supplemental oxygen delivery and CO2 monitoring during endoscopy procedures and recovery. The complete device with bite block is to be used during endoscopy procedures. The DualGuard™ Bite Block is to be removed after endoscopy, leaving the O2 delivering/CO2 sampling cannula in place for patient recovery period.	TwinGuard®, a bite block with a nasal oxygen cannula, is used during endoscopy procedures to administer continuous oxygen to the nose and mouth. After endoscopy the bite block is removed, leaving the cannula in place during recovery, to continue delivering oxygen to the nose and mouth. In addition, the TwinGuard® contains an optional accessory which collects samples of the patient's breathing at the nose and mouth to measure CO2 with a capnograph during endoscopy procedures. It is intended for adult patients.
Prescription Use?	Yes	Yes
Processes carried out	Injection moulding Tube extrusion Solvent bonding Packaging	Injection moulding Tube extrusion Solvent bonding Packaging
Component interactions	O2 & CO2 Tube – non-Invasive, skin contact (intact) and Externally communicating. Limited use (<24hr) Connectors – skin contact (hands), limited use (<24h) Bite Block – invasive (natural orifice) mucosal membrane, limited use(<24h)	O2 & CO2 Tube – non-Invasive, skin contact (intact) and Externally communicating. Limited use (<24hr) Connectors – skin contact (hands), limited use (<24h) Bite Block – invasive (natural orifice) mucosal membrane, limited use(<24h)
Storage conditions	Store in a cool, dry place out of direct sunlight	Store in a cool, dry place out of direct sunlight
Available sizes	Adult	Adult
Available lengths	2.0m	2.0m
O2 tube dimensions	ID: 3.9mm OD: 5.0mm	ID: 3.9mm OD: 5.6mm
CO2 tube dimensions	ID: 1.2mm OD: 2.7mm	ID: 1.4mm OD: 2.7mm
Colour	Blue, Orange, Clear/Colorless	Green, Clear/ Colorless

Although very similar in design and function, there are some differences (described below) between the Flexicare DualGuard™ and the predicate device. However, these differences do not raise and new safety or effectiveness issues.

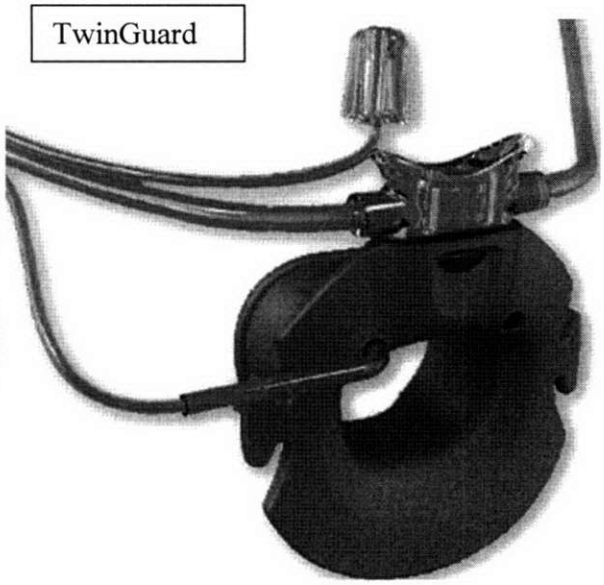
The Flexicare DualGuard™ has an over molded soft TPE section around the bite area of the bite block whilst the predicate Trawax "TwinGuard" does not have this feature.

The Flexicare DualGuard ™ also differs from the Trawax "TwinGuard" predicate as DualGuard™ includes a nasal CO2 sampling cannula. This cannula is bonded side-by-side with the **Oxygen** delivering cannula and samples **CO2** through its prongs that locate beneath the nostrils. This nasal sampling cannula is not present on the predicate device, which obtains its nasal CO2 samples via a plug & monitoring line that is inserted into one nostril. This does however restrict oxygen delivery to one nostril.

DualGuard™



TwinGuard



DualGuard™ also features a self sealing Y-Piece, allowing CO2 to be sampled from the nose and mouth simultaneously or from the nose only, without the need to cap a disconnected port.

Another difference between DualGuard™ and its predicate device "TwinGuard", although not critical, is strap securing locations. Flexicare's device features flexible molded wings which the strap secures onto, which keeps the bite block secure in the mouth. The "TwinGuard" features a hook on location each side of the bite block to secure head strap.

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Summary of Testing:

DualGuard™ has been evaluated in accordance with standards listed in table:

Test	Standard / Pre-Determined Acceptance Criteria	Outcome
Visual inspection	Pre-Determined Acceptance Criteria	All Samples pass
Tubing flow resistance	BS EN13544-2: 2002 +A1:2009.	All Samples pass
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.	All Samples pass
Dead Space	Pre-Determined Acceptance Criteria	DualGuard Dead space is less than marketed predicate.
Dimensional inspection of luer conical	ISO 594-2 (BS EN 1707:1997)	All Samples pass
Gauging tests on luer		
Liquid leakage from luer		
Air leakage from luer		
Luer separation force		
Luer unscrewing torque		
Luer ease of assembly		
Luer resistance to overriding		
Luer testing for stress cracking		
Leak testing of all bonded components	Pre-Determined Acceptance Criteria	All Samples pass
Co2 monitoring function test	Pre-Determined Acceptance Criteria	All Samples pass
Tensile testing – CO2 & O2 lines to connector and/or cannula prongs	Pre-Determined Acceptance Criteria	All Samples pass
Dimensional characteristics	Pre-Determined Acceptance Criteria	All Samples pass
Accelerated age testing	ASTM F1980	All Samples pass
Cytotoxicity, Irritation, sensitization	BS EN ISO 10993-10:2010	All Samples pass
	BS EN ISO 10993-5:2009	All Samples pass

All Samples passed the performance testing when tested against methods and criteria from pre-determined acceptance criteria In-House test methods and relevant BS EN, ISO & ASTM FDA recognized standards.

The results of this testing show that DualGuard™ passes all performance tests and performs at least as well as the marketed predicate device "TwinGuard" by Trawax.

The conclusions drawn from the nonclinical performance comparison testing demonstrate that DualGuard™ is as safe, as effective, and performs as well as or better than the legally marketed Predicate device "TwinGuard" by Trawax.

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

April 10, 2014

Flexicare Medical Limited
c/o Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K140473
Trade/Device Name: DualGuard™
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: II
Product Code: CCK, MNK, CAT
Dated: March 25, 2014
Received: March 26, 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.

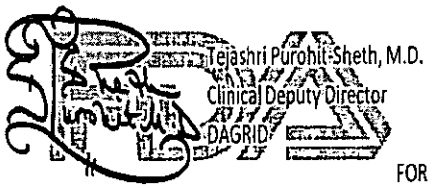
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

Please be advised that FDA's issuance of a substantial equivalence 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 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. 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

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental 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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K140473

Device Name
DualGuard™

Indications for Use *(Describe)*

DualGuard™ is intended for use in Adult patients who require supplemental oxygen delivery and CO2 monitoring during endoscopy procedures and recovery.
The complete device with bite block is to be used during endoscopy procedures.
The DualGuard™ Bite Block is to be removed after endoscopy, leaving the O2 delivering/CO2 sampling cannula in place for patient recovery period.

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
2014.04.09 12:58:53 -04'00'