DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 17, 2017

Venture Therapeutics, Inc.
Marilyn Friedly
Director, Regulatory Affairs
6525 Doubletree Avenue
Columbus, Ohio 43229

Re: K161250
Trade/Device Name: OC-FLEX Flexible Intraoral Cannula
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK
Dated: February 13, 2017
Received: February 16, 2017

Dear Marilyn Friedly:

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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161250

Device Name
OC-FLEX® Flexible IntraOral Cannula

Indications for Use *(Describe)*

The OC-FLEX® Flexible IntraOral Cannula is an adjunct to oxygen therapy with its primary function being that of delivering low flow oxygen to a patient while providing a means to sample expired gas. It is intended for use in patients requiring oxygen therapy to improve blood oxygen levels while monitoring expired gas to determine ventilatory rate.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Venture Therapeutics

510(k) SUMMARY

A. Submitter

Venture Therapeutics, Inc.
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B. Contact Person

Marilyn A. Friedly
Director, Regulatory Affairs
mfriedly@venturetherapeutics.com

C. Date Prepared

March 17, 2017

D. Device Name

Proprietary Name:	OC-FLEX® Flexible IntraOral Cannula
Common Name:	Oxygen Delivery / Carbon Dioxide Sampling Cannula
Classification Name:	Carbon Dioxide Gas Analyzer (accessories)
Regulatory	Class II per 21 CFR 868.1400
Product Code	CCK

E. Predicate Device

Hudson RCI® Softech® Bi-Flo® Cannula (K961150)

F. Device Description

The OC-FLEX® Flexible IntraOral Cannula is a disposable, non-sterile, single use device that is intended to provide a means for sampling exhaled gases from a patient (i.e., end-tidal CO_2) with the option to simultaneously or independently deliver supplemental gas therapy (i.e., O_2).

The device design consists of dual, conjoined PVC tubing united by an end cap providing two separate gas pathways. One portion of the tubing is dedicated to supplying gas from a gas source to the patient as required by the prescribed therapy. The other portion of the tubing is dedicated to the sampling of exhaled gas from the patient to a gas analyzer (i.e., a capnograph) for end-tidal CO_2 monitoring. The design of the OC-FLEX® Flexible IntraOral Cannula incorporates a flexible wire located inside a separate, dedicated lumen in the gas supply tubing in conjunction with an end cap comprised of a filter. The flexible wire feature of the cannula is isolated from the delivery gas as well as the exhaled gas in a dedicated lumen within the gas supply tubing. This allows

customizable positioning of the cannula for delivery and sampling of gas. This design is engineered to provide the practitioner flexibility and mobility during the procedure. The end cap minimizes occlusion during sampling of exhaled gas and segregates the gas sampling from the supplied gas for therapy to the patient. This design feature allows the delivery of the prescribed gas (i.e., oxygen) to the oral cavity. The end cap design features a 3-micron hydrophobic filter, which prevents the transfer of water vapor or other body fluid from the patient down to the monitoring line and into the gas sampling equipment.

The OC-FLEX® Flexible IntraOral Cannula is a single patient device, designed for use by one patient over a single course of treatment. The device is available with either a male luer connector or female luer connector. The device is supplied in a sealed poly bag in a non-sterile state and is not to be sterilized.

G. Intended Use

ELEMENT	OC-FLEX® Flexible IntraOral Cannula
Indications for use	The OC-FLEX® Flexible IntraOral Cannula is an adjunct to oxygen therapy with its primary function being that of delivering low flow oxygen to a patient while providing a means to sample expired gas. It is intended for use in patients requiring oxygen therapy to improve blood oxygen levels while monitoring expired gas to determine ventilatory rate.
Environment of Use	Hospital, sub-acute and pre-hospital settings
Patient Population	Adult patient requiring exhaled gas monitoring and/or supplemental oxygen
Oxygen	Oxygen is provided to the patient via the oral cannula connecting the oxygen source to the patient
Gas Sampling	The gas sampling line is intended to interface with the patient via the oral cannula and a standard luer connector to the gas monitor
Product Labeling	O_2 / CO_2 Oral Cannula
Single use or reusable	Single use
Shelf life	2 years

H. Description of Substantial Equivalence

The components found in the OC-FLEX® Flexible IntraOral Cannula have been used in legally marketed devices. Substantial equivalence was determined based on the prior use of components in legally marketed devices in conjunction with extensive biocompatibility data. Substantial equivalence of effectiveness was determined utilizing comparative bench studies of the OC-FLEX® Flexible IntraOral Cannula and predicate device.

The OC-FLEX® Flexible IntraOral Cannula has been designed with a slight difference from the predicate device in the location of the delivery of gas and the sampling of the exhaled breath. The predicate device delivers gas and samples the exhaled breath via the nasal passage and the OC-FLEX® Flexible IntraOral Cannula delivers gas and samples the exhaled breath via the oral

cavity. In addition to typical O_2 delivery and end-tidal CO_2 for the majority of patients, the location difference allows for monitoring the exhaled breath for specific types of patients (e.g. the mouth-breathing patient, the patient with a deviated septum, or the patient receiving a facial reconstructive procedure that impedes the use of a nasal cannula). Effectiveness of the device suitably compares to that of the predicate as demonstrated in bench testing.

The OC-FLEX® Flexible IntraOral Cannula incorporates a flexible wire located inside a separate, dedicated lumen in the gas supply tubing in conjunction with an end cap comprised of a filter. The flexible wire feature of the cannula is isolated from the delivery gas as well as the exhaled gas in a dedicated lumen within the gas supply tubing. This allows variable positioning of the cannula for delivery and sampling of gas. To verify the biocompatibility of the materials used in the manufacturing of the OC-FLEX® Flexible IntraOral Cannula, extensive biocompatibility testing was conducted. The testing demonstrated that the materials used have no cytotoxic effect. The testing also confirmed that the materials used are non-irritants and do not have sensitization effects.

The following common characteristics further summarize substantial equivalence:

- The OC-FLEX® Flexible IntraOral Cannula has the same intended use as the predicate device.
- Both the OC-FLEX® Flexible IntraOral Cannula and the predicate device are single patient use devices.
- Both the OC-FLEX® Flexible IntraOral Cannula and the predicate device are supplied non sterile in individually packaged poly bags.
- Both the OC-FLEX® Flexible IntraOral Cannula and the predicate device utilize the same main design technology: the use of PVC tubing for the delivery of therapy gas and the transport of sampling exhaled gas.
- Neither the OC-FLEX® Flexible IntraOral Cannula nor the predicate device is a life-supporting or life-sustaining device.
- Neither the OC-FLEX® Flexible IntraOral Cannula nor the predicate device use software or are mechanically or electronically driven.
- Both the OC-FLEX® Flexible IntraOral Cannula and the predicate device utilize the same manufacturing process for their components: injection molding and extruded plastic.
- Both the OC-FLEX® Flexible IntraOral Cannula and the predicate device utilize a similar primary material: PVC tubing (the OC-FLEX® Flexible IntraOral Cannula uses DEHP-free PVC).
- Both the OC-FLEX® Flexible IntraOral Cannula and the predicate device utilize male and female luer connectors.

Venture Therapeutics

ELEMENT	OC-FLEX® FLEXIBLE INTRAORAL CANNULA-New Device	HUDSON RCI SOFTECH BI-FLO	PERFORMANCE TESTING
510k	K161250	K961150	N/A
Intended Use	This device is an adjunct to oxygen therapy with its primary function being that of delivering low flow oxygen to a patient while providing a means to sample expired gas. It is intended for use in patients requiring oxygen therapy to improve blood oxygen levels while monitoring expired gas to determine ventilatory rate.	Same	N/A
Prescription	Yes	Yes	N/A
Environment of Use	Hospital, sub-acute and pre-hospital setting	Same	N/A
Technological characteristic	Provide a means to deliver exhaled end-tidal CO_2 to a capnograph via tubing from the oral cavity Provide means to deliver continuous medical grade O_2 as required via tubing to the oral cavity	Provide a means to deliver exhaled end-tidal CO_2 to a capnograph via tubing from nasal prong Provide means to deliver continuous medical grade O_2 as required via tubing to nasal prong	$EtCO_2$ Performance Testing with Simultaneous Oxygen Delivery $EtCO_2$ Performance Testing with Simultaneous Oxygen Delivery
Design	Cannula made of dual, conjoined tubing connected with an end cap: One portion of tubing is for the sampling of end-tidal CO_2 One portion of tubing is for the delivery of the oxygen to the patient Isolated flexible wire for cannula positioning 3-micron hydrophobic filter	Cannula made of dual, conjoined tubing connected to end piece made of two nasal prongs: One portion of tubing is for the sampling of end-tidal CO_2 One portion of tubing is for the delivery of the oxygen to the patient No flexible wire No filter	Biocompatibility Testing: Cytotoxicity Sensitization; Intracutaneous Irritation Volatile Organic Compound (VOC) Testing Particulate Matter Testing
Material of construction	PVC (Phthalate free) Not made with natural rubber latex	PVC Not made with natural rubber latex	N/A

ELEMENT	OC-FLEX® FLEXIBLE INTRAORAL CANNULA-New Device	HUDSON RCI SOFTECH BI-FLO	PERFORMANCE TESTING
Energy used or delivered	Not Applicable	Not Applicable	N/A
Manufacturing Process	Injection molding, Extrusion and assembly	Injection molding; Extrusion and assembly	N/A
Performance	Comparison end-tidal CO_2 results at various settings	Equivalent	$EtCO_2$ Performance Testing with Simultaneous Oxygen Delivery
Labeling	Oxygen delivery and carbon dioxide sampling cannula	Same	N/A

I. Non-Clinical Performance Data

The substantial equivalence of the OC-FLEX® Flexible IntraOral Cannula has been demonstrated via biocompatibility testing, volatile organic compound (VOC) and particulate matter testing, and comparative performance bench testing, respectively.

Biocompatibility Testing

To confirm the suitability of the materials used in the manufacture of the cannula, biocompatibility studies were performed as per ISO 10993 "Biological evaluation of medical device." These studies included the following tests:

- Cytotoxicity
- Sensitization
- Intracutaneous Irritation

The OC-FLEX® Flexible IntraOral Cannula has successfully completed the ISO 10993 testing for biocompatibility with no incidence of cytotoxicity, sensitization or intracutaneous irritation.

Volatile Organic Compound (VOC) and Particulate Matter Testing

To evaluate the safety of the dry gas pathway of the OC-FLEX® Flexible IntraOral Cannula, volatile organic compound (VOC) and particulate matter testing were performed.

The OC-FLEX® Flexible IntraOral Cannula was evaluated for VOC's using EPA methodology. Results of the VOC testing were compared against health protective toxicological values to determine the margin of safety based on patient population. All compounds identified by this testing have demonstrated levels within available recommended limits.

The OC-FLEX® Flexible IntraOral Cannula was assessed using NIOSH methodology for the determination of respirable particulate matter. Results were compared to safety values for particulate matter exposure to the patient. Particulate matter results have demonstrated levels below the recommended limits.

Performance Testing

To address any potential impact of design difference between the OC-FLEX® Flexible IntraOral Cannula and the predicate device, additional testing was performed. To demonstrate the effectiveness of the design, a comparative bench test was conducted on the OC-FLEX® Flexible IntraOral Cannula against the predicate device. The results demonstrated that the OC-FLEX® Flexible IntraOral Cannula varied less or equal to the true values when compared to the predicate device, thereby supporting the effectiveness of the device.

Study Attribute	**Description**
Test Subject	The OC-FLEX® Flexible IntraOral Cannula was tested alongside the predicate device (Hudson RCI Softech Bi-Flo Cannula)
Objective	To measure the end-tidal CO_2 values utilizing an oxygen-delivering cannula under simulated patient conditions
Acceptance Criteria	End-tidal CO_2 values shall not be statistically different (or vary less from the true end-tidal CO_2 values) than the predicate device.
Apparatus	Harvard Respiratory pump and mannequin head to simulate patient head. Cannula connected to oxygen supply line, CO_2 sensing line and CO_2 detector (capnograph)
Simulated Respiratory Setting	Respiratory rate : 8, 16, 25 bpm Tidal Volume: 750, 600, 300 ml I:E ratio (All Conditions): 1:1 (inspiration: expiration) End-Tidal Concentration: 5%
Oxygen Delivery Setting	Source flow of 0, 1, 3, and 6 liters per minute for each setting was used. The system was allowed at least 3 minutes of oxygen delivery to equilibrate prior to sampling CO_2.
Measurement	Each test was sampled three times at each combination of settings for a total of 36 tests (3 samples x 3 respiratory settings x 4 oxygen flow rates).
Results	The end-tidal CO_2 values for the OC-FLEX® Flexible IntraOral Cannula were not statistically different, or varied less from the true end-tidal CO_2 values, than the predicate product. A comparison of variances of the end-tidal CO_2 measurements from the actual values for the two devices indicates that the OC-FLEX® Flexible IntraOral Cannula has the least variance from true value when compared to the predicate device, within 95% confidence intervals.
Discussion	The OC-FLEX® Flexible IntraOral Cannula met the predetermined acceptance criteria of the test. Both the OC-FLEX® Flexible IntraOral Cannula and predicate device are intended to provide means for sampling $ETCO_2$ with the option to deliver supplemental O_2 therapy to patients. This performance test demonstrated that the OC-FLEX® Flexible IntraOral Cannula performs equally to, or better than, the predicate device in accurately capturing end-tidal CO_2, thereby supporting the substantial equivalence of the OC-FLEX® Flexible IntraOral Cannula to the predicate product.

J. Clinical Performance Data

No clinical studies were conducted on this device.

K. Conclusion

The device data and test results demonstrate the OC-FLEX® Flexible IntraOral Cannula is substantially equivalent to the predicate device.