September 12, 2023

Manoj Kumar
Consultant/Part Time Executive
45 N Fulton St
Homer, New York 13077

Re: K213767
Trade/Device Name: Endure ETCO2/02 Nasal Cannula
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK, CAT
Dated: January 8, 2023
Received: January 17, 2023

Dear Manoj Kumar:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213767

Device Name
Endure ETCO2/O2 Nasal Cannula

Indications for Use *(Describe)*

Endure ETCO2/O2 Nasal Cannula has two functions
1) It is intended to deliver supplemental Oxygen to patients and
2) to obtain CO2 sampling of exhaled air

Environment of use: The device is intended to be used in hospitals, surgery centers and other acute care centers.

Patient population: Patients requiring supplemental Oxygen and/or requiring CO2 monitoring. Intended for patients above 12 years of age.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K213767

SUMMARY ("510(k) Summary" as required by section 807.92(c).)

1. **Submitters Information:**

Company Name: Endure Industries Inc

Company Address: 45 N Fulton St

Homer, NY 13077

Contact Person: Manoj Kumar, Physician Consultant.

2. **Proprietary or Trade Name:** Endure ETCO2/O2 Nasal Cannula

   Common/Usual Name: Analyzer, gas, carbon-dioxide, gaseous phase (accessories)

   Classification Name: Analyzer, gas, carbon-dioxide, gaseous phase (accessories)

   Product Code: CCK – CFR 868.1400

   Device Class: Class II

   Additional Product Code: CAT Cannula, Oxygen Nasal

3. **Predicate Device Identification:** This pre-market notification will demonstrate that Endure Industries CO2/Oxygen sampling cannula is substantially equivalent to the predicate device listed below

   K010024 Oridion Nasal CO2/O2 Cannula

4. **Device description:**

   Endure Industries has designed an ETCO2/O2 nasal cannula and an exhaled gas sampling device. The features include sampling of CO2 from exhaled air to a capnograph. It can provide supplemental O2 and sample exhaled air at the same time. The device is configured in such a way that it has a nasal cannula with a division to deliver oxygen through one nares and sample exhaled gases through the other.

5. **Indications for Use:**

Endure ETCO2/O2 Nasal Cannula has two functions
1) It is intended to deliver supplemental Oxygen to patients and
2) To obtain CO2 sampling of exhaled air

Environment of use:

The device is intended to be used in hospitals, surgery centers and other acute care centers..

Patient population:

Patients requiring supplemental Oxygen and/or requiring CO2 monitoring. Intended for patients above 12 years of age.

6. Technological characteristics of the device compared to the predicate device:

The technological features of the predicate and proposed devices are found to be the similar as shown in the table below. The following features are discussed here:

Design: The cannula is divided to separate the CO2 sampling part from the O2 delivery area. The length of the tubing is 7 feet for both predicate and proposed devices. Both adult and pediatric types have the same length. Male or Female Luer connectors are present on both types. The length of the adaptor is 22mm x 6 mm for both devices.

Material: Both adult and pediatric tubing are made of flexible medical grade PVC as in the predicate device.

Sterilization: The device is marketed as single-use and non-sterile. This is the same for the predicate device.

Packaging configuration: The product is individually packaged in heat sealed poly bag with instructions of use and other information inserted inside as a label. 10 units are in a shipping carton.

Table of comparison			
Features	**Predicate Device ORIDION K010024**	**Endure ETCO2/O2 Nasal Cannula K213767**	**Equivalence**
Indication for use	**To sample exhaled gas via nasal cannula and simultaneously provide supplemental Oxygen near the nose and mouth for inhalation**	**Endure ETCO2/O2 Nasal Cannula has two functions 1) It is intended to deliver supplemental Oxygen to patients and 2) to obtain CO2 sampling of exhaled air**	**Indication use is exactly the same forboth pridcate device and Endure cannula. Both devices sample CO2 from exahled air and deliver Oxygen at the same time.**
Environment of use	**Hospitals, sub-acute, pre-hospital settings**	**Hospitals, sub-acute, pre-hospital settings**	**Substantially equivalent: Both devices are used in hospital, prehospital and subacute settings.**
Intended Population	**Adults and Pediatrics - Patient requiring supplemental oxygen and / or sampling of expired gases**	**Adults and Pediatrics - Patient requiring supplemental oxygen and / or sampling of expired gases**	**Substantially equivalent: Both devices are in adults and pediatrics.**
Duration of use	**Single patient use - Disposable Less than 24 hours**	**Single patient use - Disposable Less than 24 hours**	**Substantially equivalent: Both predicate and proposed devices are for single use lasting less than 24 hours.**
Single Patient Use	**Yes**	**Yes**	**Identical: Both predicate and proposed devices are for single use.**
Dispensing	**Only on prescription or as ordered by a medical provider.**	**Only as per the order of a physician or medical provider.**	**Substantially equivalent: Dispensing is allowed only as per the order of a physician or medical provider.**
Basic Component	**Nasal cannula, Oxygen tubing Gas sampling line**	**Nasal Cannula, Oxygen tubing Gas sampling line**	**Identical: Basic components are the same for both predicate device and proposed device**
Patient Interface	**Nasal cannula**	**Nasal Cannula**	**Patient interface is the same for both predicate device and proposed device**
Design	**Split / channeled nasal cannula, sampling in one and Oxygen delivery in the other**	**Split / channeled nasal cannula with sampling in one and Oxygen delivery in the other**	**Substabtially Equivalent: Split / channeled nasal cannula with sampling in one and Oxygen deliver in the other**
Material	**Flexible PVC**	**Flexible PVC**	**Identical: Material is the same for both propsed device and predicate device**
Sampling tube specifications	**Not provided ID – 0.06" / OD –0.1" Length –2"**	**ID – 0.08" / OD –0.1" Length –2"**	**Identical: We have made measurements of the predicate device and compared it to the proposed one.**
Biocomaptibility Cytotoxicity Skin Sensitivity Skin Irritation	**ISO 10993-1**	**ISO 10993-1**	**Identical test results for cytotoxicity, skin senitivity and skin irritation**
Performance Testing Luer Fitting Tensile strength End tidal CO2 measurement		**Performance Testing Luer Fitting Tensile strength End tidal CO2 measurement**	**Equivalent.**
Age Testing	**Not provided**	**Yes**	**Age testing done with cannulas manufactured in 2019 and found to be equivalent to cannulas manufactured in 2022. Such information is not available for the predicate device.**
Shelf Life	**5 years**	**3 years (Aging studied are only available to verify 3 years of shelf life)**	**Different. Although they have a difference in shelf life, both of them have the same intended use, principle of operation, performance characteristics and scientific technology. So the difference is unlikely to raise any new safety or effectiveness**
Home Use	**No**	**No**	**Identical**

7. Biocompatibility

   We have done ISO 10993 testing on the component materials of the proposed devices. The nasal cannula part of the device is considered as in contact with the patient. Therefore the following tests are necessary. This was done by an accredited laboratory.

   - Cytotoxicity
   - Sensitization
   - Intracutaneous Irritation

   The test results confirm that the material used are safe to use and does not pose any risks.

   Gas pathway test conducted in accordance with ISO 18562

8. Summary for performance testing

   Comparative CO2 sampling and ETCO2 level testing were done and was found to be similar between the predicate device and the proposed device. O2 flow rates were also compared at 2,4 and 6 LPM flow and were found to be similar. Physical measurements were also done and were found to be similar between the predicate device and the proposed one. Luer fitting was also compared and found to be similar and leak-free.

9. Conclusions: Endure Industries Inc. has demonstrated through various testing that the proposed device and predicate device can be found to be substantially equivalent. In addition, biocompatibility testing confirms the safety of the devices with regard to patient contact.