Tylenol Medical Instruments Co., Ltd
Huang Kaigen
RA Manager
3rd Floor, No. 10, Xinhua Road, Sanjiao Town
Zhong Shan,  528445 Cn

Re:  K181981
Trade/Device Name:  CO2 Sampling Line
Regulation Number:  21 CFR 868.1400
Regulation Name:  Carbon Dioxide Gas Analyzer
Regulatory Class:  Class II
Product Code:  CCK
Dated:  December 23, 2018
Received:  January 3, 2019

Dear Huang Kaigen:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Todd D. Courtney -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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K181981

Device Name
CO2 Sampling Line

Indications for Use *(Describe)*
The CO2 Sample Lines are intended to be used where exhaled gas is monitored.
The intended population: Patients requiring expired gas monitoring, adult to pediatrics
The intended environment of use:Hospital-OR, sub-acute, and pre-hospital settings

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

**FORM FDA 3881 (7/17)** Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

# 510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

| | |
|---|---|
| Date: | 2019/1/24 |
| Submitter: | Tylenol Medical Instruments Co., Ltd<br>Address: 3rd Floor, No.10, Xinhua Road, Sanjiao Town, Zhongshan City, Guangdong 528445, China |
| Contact Person: | Huang Kaigen<br>Regulatory Affairs Manager<br>Tylenol Medical Instruments Co., Ltd.<br>Email: Event789@126.com<br>Tel: +86-760-22819958<br>Fax:+86-760-22819958 |
| Device Name: | $CO_2$ Sampling Line |
| Common Name: | $CO_2$ Sampling Line |
| Regulation Number: | 21 CFR 868.1400 |
| Regulation Name: | Carbon dioxide gas analyzer |
| Product Code: | CCK |
| Regulatory Class: | Class II |
| Predicate Device(s): | K151421- Nasal $CO_2$ Sample Line; $O_2$ Delivery/$CO_2$ Sampling Nasal Cannula; Oral/Nasal $CO_2$ Sampling Cannula; $O_2$ Delivery with Oral/Nasal $CO_2$ Sampling Cannula; Divided $O_2$ Delivery/$CO_2$ Sampling Nasal Cannula and Sample Lines Lines |

**1. Intended Use**

The CO2 Sample Lines are intended to be used where exhaled gas is monitored.
The intended population: Patients requiring expired gas monitoring, adult to pediatrics.
The intended environment of use: Hospital-OR, sub-acute, and pre-hospital setting.

2. Device Description

Breath gas analysis is commonly performed to provide informatin related to a patient's condition. An example of a gas analysis often performed is capnography using an analyzer called a capnograph. Capnography is the monitoring of the time dependent respirary carbon dioxide($CO_2$) concentration, which may be used to directly monitor the inhaled and exhaled concentration of $CO_2$, and indirectly monitor the $CO_2$ concentration in a patient's blood.

$CO_2$ monitoring of patients respired gases can be used to display of information about $CO_2$ production, pulmonary(lung) perfusion, alveolar ventilation (alveoli are hollow cavities in the lungs in which gas exchange is being performed) and respiratory patterns related to a patient's condition during anesthesia.

In breath analysis systems, for example capnograraphy, breath gas can be sampled either by a mainstream or a sidestream analyzer. $CO_2$ Sampling Lines are availabe for $CO_2$ sampling when mainstream capnography is used, so as to perform a mainstream capnographic measurement of the level of $CO_2$.

The $CO_2$ Sampling Line is a sterile, disposable, singlie patient use cannula that allows sampling of patients exhaled gases. It consists of flexible extruded plastic tubes with standard connectors on each end. The cannula is a straight and flexible tube which permits the passage of a fluid such as carbon dioxide through an orifice (a buccal or nasal cavity of a patient).

In addition, the $CO_2$ sampling line is adapted used to connect between the patient's end of the breathing system and the distant analyzer, such as the capnograph monitor, along this tube, the patient's breath is continuously sampled.

Professional Doctor or Anesthesiologists utilize $CO_2$ sampling line allowing mainstream capnographic measurement in certain clinical scenarios in Hospital-OR sub-acute and pre-hospital settings.

The contact duration of $CO_2$ sampling line is less than 24h.

**3. Substantial Equivalence—Comparison to Predicate Devices**

The $CO_2$ Sampling Line described in this 510(k) has similar technological and performance characteristics to the predicate devices. The similarities and differences between the proposed and predicate devices have been identified and explained in the comparison matrix which has been included in Section 12 of this submission. These differences do not raise different questions of safety and effectiveness.

**Similarities Between Proposed and Predicate Device**

The proposed $CO_2$ Sampling Line and the predicate devices, K151421 Nasal $CO_2$ Sample Line; $O_2$ Delivery/$CO_2$ Sampling Nasal Cannula; Oral/Nasal $CO_2$ Sampling Cannula; $O_2$ Delivery with Oral/Nasal $CO_2$ Sampling Cannula; Divided $O_2$ Delivery/$CO_2$ Sampling Nasal Cannula and Sample Lines, have the similar intended use, principle of operation, performance characteristics and scientific technology.

**Differences Between Proposed and Predicate Device**

The differences between proposed and predicate devices, as shown in the following:

**Shelf Life**

The proposed device's shelf life is 5 years, for which, the performance testing after simulated 5 year aging, while the predicate device's shelf life is 3 years.

The only minor difference between the proposed device and the predicate devices is the shelf

life. The proposed device is tested after simulated 5 year aging, while the predicate device is tested after 3 year aging.

Although they have small difference in shelf life, both of them are used where exhaled gas is monitored. They have the same intended use, principle of operation, performance characteristics and scientific technology. So the difference does not raise different questions of safety or effectiveness.

There are many FDA cleared $CO_2$ Sampling Lines which are available in various shelf life. Therefore, this different shelf life does not raise different questions of safety or effectiveness concerns as both devices are intended to be used in the same populations.

The non-clinical data support the substantial equivalence of the proposed device. Also test results demonstrate that the proposed device is as safe and effective as the predicate and therefore substantially equivalent to the predicate device. The proposed device has the same classification information, similar intended use and technological characteristics as compared to the predicate devices.

Therefore the proposed $CO_2$ Sampling Line are substantially equivalent to the K151421 Nasal $CO_2$ Sample Line; $O_2$ Delivery/$CO_2$ Sampling Nasal Cannula; Oral/Nasal $CO_2$ Sampling Cannula; $O_2$ Delivery with Oral/Nasal $CO_2$ Sampling Cannula; Divided $O_2$ Delivery/$CO_2$ Sampling Nasal Cannula and Sample Lines. The proposed device has the same classification information, similar intended use and technological characteristics as compared to the predicate devices.

**4. Summary of Non-Clinical Performance Testing**

The following performance testing was conducted for the the $CO_2$ Sampling Line:

**1) General performance testing including:**

※ Dimensions
※ Back pressure(flow rates)
※ Bond Strength(tensile strength)
※ Liquid leakage
※ Air leakage
※ Separation force
※ Unscrewing torque
※ Ease of assembly
※ Resistance to overring
※ Stress cracking

Testing datas and results are included in this submission, and demonstrated that the $CO_2$ Sampling Line meets all the pre-determined testing and acceptance criteria.

**2) Biocompatibility testing as per ISO 10993-1:2009 including:**

※ Cytotoxicity as per ISO 10993-5:2009
※ Irritation as per ISO 10993-10:2010
※ Sensitization as per ISO 10993-10:2010

Biocompatibility testing reports are included in this submission, and demonstrated that the device componets that are in contact with the patient are biocompatible.

**3) Sterilization and Shelf-Life:**

※ Sterilization as per ISO 11135:2014
※ EO residue as per ISO 10993-7:2008
※ Sensitization as per ISO 10993-10:2010

**4) Packaging Testing:**

※ Tensile seal strength test as per ISO 11607:2006
※ Packaging Integrity Test as per ISO 11607:2006
※ Peel/Open testing as per ISO 11607:2006

**Conclusions Drawn from the Non-Clinical Testing**

The results of these tests demonstrate that the device is as safe, as effective, and performs as well as the identified predicates and support a determination of substantial equivalence.

## 5. Conclusion

The $CO_2$ Sampling Line is substantially equivalent to predicate devices K151421 Nasal $CO_2$ Sample Line; $O_2$ Delivery/$CO_2$ Sampling Nasal Cannula; Oral/Nasal $CO_2$ Sampling Cannula; $O_2$ Delivery with Oral/Nasal $CO_2$ Sampling Cannula; Divided $O_2$ Delivery/$CO_2$ Sampling Nasal Cannula and Sample Lines. Based on the intended use, principle of operation, performance characteristics, and technological characteristics, the proposed $CO_2$ Sampling Line is substantially equivalent to and as safe, as effective and performs as the legally marketed predicate devices.

# Substantial Equivalence Discussion

This comparison table identifies the similarities and differences of the proposed CO2 Sampling Line device to the legally marketed predicate K151421 Nasal CO2 Sample Line, Oral Nasal CO2 Sampling Cannula, O2 Oral/Nasal Co2 Cannula, Sample Lines devices to which substantial equivalency is claimed.

**Table 1 – Comparison between proposed CO2 Sampling Line & K151421 Nasal CO2 Sample Line, Oral Nasal CO2 Sampling Cannula, O2 Oral/Nasal Co2 Cannula, Sample Lines**

| **Comparison between proposed device and predicate devices** | | | |
|---|---|---|---|
| Element of Comparison | Proposed Device | Predicate Device | Discussion of Differences |
| Device Name | $CO_2$ Sampling Line | Nasal CO2 Sample Line, Oral Nasal CO2 Sampling Cannula, O2 Oral/Nasal Co2 Cannula, Sample Lines | --- |
| 510K Number | K181981 | K151421 | --- |
| Regulatory Class | Class II | Class II | Identical |
| Classification Regulation | 21CFR 868.1400 | 21CFR 868.1400 | Identical |
| Classification Pannel | Anesthesiology | Anesthesiology | Identical |
| Product Code | CCK | CCK | Identical |

| | | | |
|---|---|---|---|
| Indications Use/Intended Use | The Sample Lines are intended to be used where exhaled gas is monitored. | The Sample Lines are intended to be used where exhaled gas is monitored. | Identical |
| Directions for Use | Prescription Use | Prescription Use | Identical |
| Contact Duration | Less than 24h | Less than 24h | Identical |
| Inner Diameter (±0.2mm) | 1.0mm | 1.0mm | Identical<br>The modified devices use the same molds and are unchanged from the predicate devices |
| Outer Diameter (±0.2mm) | 2.5mm | 2.5mm | |
| Length (±60mm) | 3250mm | 3250mm | |
| Back Pressure (flow rates) | Maximum back pressure was found to be less than 2 psi. | Maximum back pressure was found to be less than 2 psi. | Identical |
| Bond Strength (tensile strength) | The bond strength test achieved over 2 times the minimum allowable value. | The bond strength test achieved over 2 times the minimum allowable value. | Identical |
| Patient Population | Patients requiring expired gas monitoring, adult to pediatrics | Patients requiring supplemental oxygen and/or expired gas monitoring, adult to pediatrics | Identical |
| Patient contact Material | Tube-PVC | Tube-PVC | Identical |

| | | | |
|---|---|---|---|
| Connector | Stand Connector | Stand Connector | Identical |
| Design Features | Tubing, Connector | Tubing, Connector | Identical |
| Single patient, disposable | Yes | Yes | Identical |
| Shelf Life | 5 year | 3 year | Different.<br>Although they have small difference in shelf life, both of them are used where exhaled gas is monitored. They have the same intended use, principle of operation, performance characteristics and scientific technology. So the difference does not raise any new safety or effectiveness. |
| Method of sterilization | Ethylene Oxide Sterilized per ISO 11135 | Ethylene Oxide Sterilized per ISO 11135 | Identical |
| The Sterility Assurance Level | SAL $10^{-6}$ | SAL $10^{-6}$ | Identical |
| EO residual | The ethylene oxide residual is conform to ISO 10993:7 for Limited Exposure Devices of 4mg/device for EO and 9mg/device for ECH | The ethylene oxide residual is conform to ISO 10993:7 for Limited Exposure Devices of 4mg/device for EO and 9mg/device for ECH | Identical |
| Materials Biocompatibility | ISO 10993-1<br>Cytotoxicity testing per 10993-5<br>Sensitization testing per ISO 10993-10 | ISO 10993-1<br>Cytotoxicity testing per 10993-5<br>Sensitization testing per ISO 10993-10 | Identical |

| | | | |
|---|---|---|---|
| | Irritation Test per ISO 10993-10<br>All the test passed | Irritation Test per ISO 10993-10<br>All the test passed | |
| Applied Standards | ISO 11607-1<br>ISO 11607-2<br>ISO 10993-1<br>ISO 10993-5<br>ISO 10993-7<br>ISO 10993-10<br>ISO 11135<br>ISO 594-2 | ISO 11607-1<br>ISO 11607-2<br>ISO 10993-1<br>ISO 10993-5<br>ISO 10993-7<br>ISO 10993-10<br>ISO 11135<br>ISO 594-2 | Identical |
| Packaging | Sterile | Sterile | Identical |
| Environments of Use | Hospital-OR, sub-acute, and pre-hospital settings | Hospital-OR, sub-acute, and pre-hospital settings | Identical |
| Surface | Smooth, Transparent | Smooth, Transparent | Identical |
| Principles of operation | The $CO_2$ sampling line is adapted used to connect between the patient's end of the breathing system and the distant analyzer, such as the capnograph monitor, along this tube, the patient's breath is continuously sampled | The $CO_2$ sampling line is adapted used to connect between the patient's end of the breathing system and the distant analyzer, such as the capnograph monitor, along this tube, the patient's breath is continuously sampled | Identical |

## Table 2 - Determination of Substantial Equivalence

| | | |
|---|---|---|
| Do predicates have same indication statements? | Yes | The $CO_2$ Sampling Line and its predicates are intended to be used in the same manner for the same purpose. Therefore $CO_2$ Sampling Line has the same intended use and is substantially equivalent. |
| Do predicates have same technological characteristics? | Yes | The $CO_2$ Sampling Line offers the same technological characteristics as the predicate device. |
| Are descriptive characteristics precise enough to ensure equivalence | Yes | Information concerning the descriptive characteristics of the $CO_2$ Sampling Line and its predicates are provided in **Table 1**. This shows that all features of $CO_2$ Sampling Line exist in its predicates. |

**Similarities Between Proposed and Predicate Device**

The proposed $CO_2$ Sampling Line and the predicate devices, K151421 Nasal $CO_2$ Sample Line; $O_2$ Delivery/$CO_2$ Sampling Nasal Cannula; Oral/Nasal $CO_2$ Sampling Cannula; $O_2$ Delivery with Oral/Nasal $CO_2$ Sampling Cannula; Divided $O_2$ Delivery/$CO_2$ Sampling Nasal Cannula and Sample Lines, have the similar intended use, principle of operation, performance characteristics and scientific technology.

**Differences Between Proposed and Predicate Device**

The differences between proposed and predicate devices, as shown in the following:

**Shelf Life**

The proposed device's shelf life is 5years, for which, the performance testing after simulated 5 year aging, while the predicate device's shelf life is 3 years.

The only minor difference between the proposed device and the predicate devices is the shelf life. The proposed device is tested after simulated 5 year aging, while the predicate device is tested after 3 year aging.

Although they have small difference in shelf life, both of them are used where exhaled gas is monitored. They have the same intended use, principle of operation, performance characteristics and scientific technology. So the difference does not raise any new safety or effectiveness..

There are many FDA cleared $CO_2$ Sampling Lines which are available in various shelf life. Therefore, this different shelf life does not raise any new safety or effectiveness concerns as both devices are intended to be used in the same populations.

The non-clinical data support the substantial equivalence of the proposed device. Also test results demonstrate that the proposed device is as safe and effective as the predicate and therefore substantially equivalent to the predicate device. The proposed device has the same classification information, similar intended use and technological characteristics as compared to the predicate devices.

## Summary and Conclusion

The minor differences in the device do not introduce different questions of safety and effectiveness. Changes or modifications to the device outside its intended use should not be done as this could affect the safety and effectiveness of the device. The $CO_2$ Sampling Line has demonstrate compliance to the standards they were tested to. All of the testing performed are described and summarized in Section 18. All results demonstrate that the CO2 Sampling Lines is equivalent to the predicate devices in capability and it meets all of the standard test requirements.

Therefore the proposed $CO_2$ Sampling Lines are substantially equivalent to the Nasal CO2 Sample Line; O2 Delivery/CO2 Sampling Nasal Cannula; Oral/Nasal CO2 Sampling Cannula; O2 Delivery with Oral/Nasal CO2 Sampling Cannula; Divided O2 Delivery/CO2 Sampling Nasal Cannula and Sample Lines Lines (K151421). The proposed device has the same classification information, similar intended use and technological characteristics as compared to the predicate devices.