K961150

HUDSON RCI®

SEP 10

SUMMARY OF SAFETY AND EFFECTIVENESS

March 21, 1996

Hudson Respiratory Care Inc.
27711 Diaz Road, P.O. Box 9020
Temecula, California 92589-9020

Tel: (909) 676-5611
Fax: (909) 676-1578

Official Contact: Arden Morley
Director of Regulatory Affairs

Proprietary or Trade Name: CO_2 , Oxygen Nasal Cannula

Common/Usual Name: Cannula

Intended Device: CO_2 , Oxygen Nasal Cannula

Predicate Device:

SALTER LABS Oxygen Delivery - CO_2 Sampling Nasal Cannula
K 892406 and K 863883

Device Description

The Hudson RCI nasal cannula with gas sampling port has bifurcated nares that channel oxygen delivery through both nasal prongs while allowing sampling of the patient's exhaled gas from both nasal prongs. Oxygen is delivered to the Cannula during all phases of ventilation through the base of the cannula and is directed through the lower halves of each nasal prong into the nasal pharynx. During exhalation, oxygen continues to flow into the nasal pharynx through these lower prong halves. When the gas sampling line is connected to an expiratory gas monitor, a small amount of gas is continuously withdrawn from the nasal pharynx through the upper halves of both nasal prongs. Part of this gas exits one side of the cannula and is routed via a small-bore gas sampling line to the expired gas monitor.

Intended Use

The Hudson RCI 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. No difference in intended use between the Hudson RCI and Salter Labs product has been identified.

Patient Population

The Cannula may be used on patient populations ranging from infant to adults that require low flow oxygen therapy and expired gas monitoring. No difference in patient population between the Hudson RCI and Salter Labs product has been identified.

Comparison of Technological Characteristics

The Cannula is a modification of feature and design of the SALTER LABS Oxygen Delivery/CO_2 Sampling Cannula. The main difference between the Cannula and the predicate device is that the latter delivers oxygen through one nasal prong and samples CO_2 from the other prong while the Hudson RCI Cannula will perform both functions through each nasal prong. However, the Hudson RCI Cannula and predicate device Cannula operate in a similar manner in that they each deliver a gas, usually oxygen, while providing a means to sample exhaled gas. No difference in technological characteristics between the Hudson RCI and Salter Labs product that would affect safety or effectiveness has been identified.

Conclusion

Hudson RCI has designed and manufactured the Cannula to objective criteria and believes that it is substantially equivalent to the SALTER LABS Oxygen Delivery CO_2 Sampling Cannula which has been identified as a legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 5 2001

Ms. Sheryl Saenz
Hudson Respiratory Care, Inc.
27711 Diaz Road
P.O. Box 9020
Temecula, CA 92589

Re: K961150
Trade/Device Name: Double Lumen Oxygen Delivery Gas Sampling Nasal Cannula
Regulation Number: 868.1400
Regulatory Class: II (two)
Product Code: 73 CCK

Dear Ms. Saenz:

This letter corrects our substantially equivalent letter of September 10, 1996, regarding the Double Lumen Oxygen Delivery Gas Sampling Nasal Cannula. Our letter identified the product code as 73 CAT. This is in error; the correct product code is 73 CCK as indicated above.

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

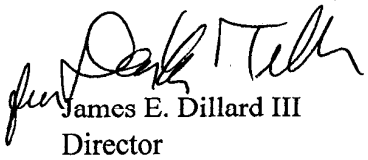
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory

action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to continue marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K961150

Device Name: Hudson RCI Gas Sampling Oxygen Nasal Cannulae

Indications for Use:

The Hudson RCI Gas Sampling Oxygen Nasal 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.

Lark Medos 6-21-96

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)