K130379

510(k)
Summary

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|---|---|---|
| Sponsor: | Rollins Medical Solutions, Inc. | 807.92(a)(1) |
| Company Address: | 1930 Village Center Circle PMB 3-314<br>Las Vegas, NV 89134 | |
| Telephone: | 702-686-1803 | |
| Contact Person: | Michael Schlachter, MD | |
| Summary Preparation Date: | October 8, 2013 | |

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|---|---|---|
| Device Name: | | 807.92(a)(2) |
| Trade Name: | Rollins 7 Oxygen Mask | |
| Common/Usual Name: | Oxygen Mask | |
| Classification Name: | Mask, Oxygen | |
| Regulation Number: | 21 CFR 868.5630 | |
| Product Code: | CAF | |
| Device Classification: | Class II | |
| Review Panel: | Anesthesiology | |

Predicate Device

| Manufacturer | Brand Name | 510(k) Number |
|---|---|---|
| Teleflex Medical, Inc. | Neb-U-Mask® | K080230 |

Device Description

The Rollins 7 Oxygen Mask consists of the following features: 1) mask, 2) strap holes, 3) swivel, 4) oxygen inlet, 5)oxygen inlet cap, 6) oxygen outlet diverter, 7) adapter body, 8) fenestration opening slits on both sides of the mask, 9) opening at the chin area, 10) MDI (metered dose inhaler) port hole inlet and insert locks in place, 11) adapter inlet bottom cap, 12) nebulizer inlet, 13) oxygen tubing, 14) oxygen mask inlet for connecting the adapter, and 15) design nipples (left and right) 16) oxygen tubing with one end universal connector and the other end standard oxygen connector 17) oxygen flow rate to $FiO_2$ label attached to universal connector end.

Indications for Use

The Rollins7 Oxygen Mask is placed over the nose and mouth to administer oxygen and aerosol therapy via nebulizer only. The Rollins7 Oxygen Mask is for adult use only.

Contraindication: Rollins 7 Oxygen Mask should not be used with Metered Dose Inhalers.

Substantial Equivalent Comparison 807.92(a)(6)

Discussion of technical characteristics between the Rollins7 Oxygen Mask and the Predicate Oxygen Mask

A flow rate study was performed to ensure Rollins7 Oxygen mask provided the same FIO2 at various liters per minute settings as the predicate devices. The results demonstrated that the Rollins7 Oxygen mask delivers similar results at all settings.

Rollins 7 Oxygen Mask has a feature that allows for the use of a Naso-gastric tube, suctioning, oral care, endoscopies, and drinking through a straw by providing an opening in the chin area of the mask. This feature is fully describe in Section 11 11.2 and is a feature of convenience for the healthcare professional and does not in any way negatively affect its use as a simple oxygen mask or aerosol mask.

Comparative Non-Clinical Testing

Two cascade impactor studies were performed comparing the Rollins7 Oxygen Mask to the Hudson RCI Neb-U-Mask to ensure similar delivery of respirable particle dose for several highly used respiratory drugs. The results demonstrated that the Rollins7 Oxygen Mask had similar delivery of respirable particle dose of each drug tested as those of the predicate devices.

Performance Testing 807.92(b)(1)

- ISO 10993-5 Cytotoxicity Test – Agar Diffusion (Section 15)
- Flow Rate Testing (Section 18)
- Cascade Impactor Study Comparing the Adult Rollins7 Oxygen Mask and Predicate Mask from Hudson RCI on a Human Model

Clinical Testing 807.92(b)(2)

No clinical tests were conducted.

Conclusions 807.92(b)(3)

Based on the predicate product comparison table of similar indications for use, product features, performance claims, discussion of the technological differences of the Rollins7 Oxygen Mask versus the predicate masks and the results of flow rate testing and cascade impactor studies Rollins Medical Solutions has concluded that the Rollins7 Oxygen Mask is substantially equivalent to the predicate devices and introduces no new issues of safety and effectiveness.

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

October 9, 2013

Rollins Medical Solutions, Incorporated
C/O Mr. EJ Smith
Consultant
Smith Associates
1468 Harwell Avenue
CROFTON, MD 21114

Re: K130379
Trade/Device Name: Rollins7 Oxygen Mask
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: August 29, 2013
Received: September 6, 2013

Dear Mr. Smith:

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.

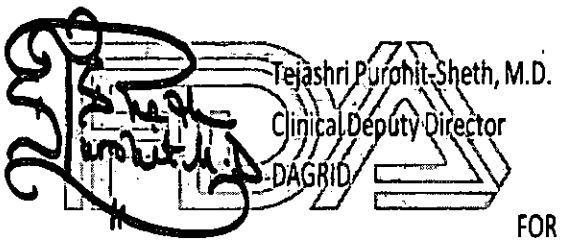
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K130379

Device Name: Rollins7 Oxygen Mask

Indications for Use:

The Rollins7 Oxygen Mask is placed over the nose and mouth to administer oxygen and aerosol therapy via nebulizer only. The Rollins7 Oxygen Mask is for adult use only.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Anya C. Harry -S

Digitally signed by Anya C. Harry -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Anya C. Harry -S, 0.9.2342.19200300.100.1.1=0011315590
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