K 050918

JUN 6 - 2005

KOO AMERICAS, Inc.

Substantial Equivalence 510(k) Summary

Koo Valve PEEP

To Whom It May Concern:

Date: 5/26/05

Submitter/ Contact Name and Address
William Slevin
Koo Americas, Inc
1050 Suite C
Nine North Drive
Alpharetta, GA 30004

Tel: (770) 360-0911

Trade Name: Koo Americas Valve PEEP

Classification Name: Breathing attachment – positive end expiratory pressure

Common/ Usual Name: PEEP Valve

Predicate Legally Marketed Device: Mercury Medical PEEP Valve

Intended Use

The Koo Americas valve PEEP is intended as a single-patient use device to provide positive-end expiratory pressure or Continuous Positive Airway Pressure when used with masks and manual resuscitators. The device is adjustable from 0cm to 20cm H_2O pressure.

Description of the Device:

The Koo Americas Valve PEEP is an adjustable valve, which is placed in a circuit and provides for positive end expiratory pressure for the patient. It is spring actuated and is a single patient use device. It is clear in construction allowing confirmation of functionality. Graduated markings allow for confirmation of settings. A convenience connector is provided to allow for conversion to 22mm. The connector is a male 30mm that connects to the female Peep Valve to provide 22mm.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 6 - 2005

Mr. William Slevin
Quality Contractor
Koo Americas, Incorporated
1050-C Nine North Drive
Alpharetta, Georgia 30004

Re: K050918
Trade/Device Name: Valve Peep
Regulation Number: 21 CFR 868.5965
Regulation Name: Positive End Expiratory Pressure Breathing Attachment
Regulatory Class: II
Product Code: BYE
Dated: April 4, 2005
Received: April 12, 2005

Dear Mr. Slevin:

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.

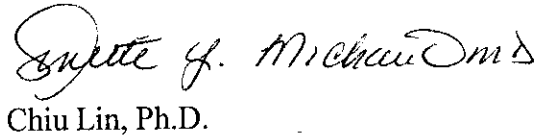
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K 050918**

Device Name: **Valve Peep**

Indications For Use: **The Koo PEEP valve is intended as a single-patient use device to provide positive-end expiratory pressure or Continuous Positive Airway Pressure when used with masks and manual resuscitators. The device is adjustable from 0cm to 20cm H_2O pressure.**

Prescription Use ✓ (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K050918