K090915

510 (K) SUMMARY

NOV 18 2009

Manufacturer	Cardinal Health 1500 Waukegan Road McGaw Park Illinois 60085
Contact	Kimberly Southwell 760-778-7280 (phone/fax)
Summary Date	March 18 2009
Device Trade Name	Sterile Water for Inhalation Flex Bag USP
Device Common/ Classification Name	Humidifier Respiratory Gas / Sterile Water for Inhalation
Regulation Number	868 5450
Product Code	BTT
Device Class	Class II
Classification Panel	Anesthesiology
Predicate Device	The predicate device(s) are K780381 Respiratory Therapy Solutions – Flexible K853146 Prefilled Respiratory Therapy Humidifier containing Sterile Water for Inhalation USP K760584 U Mid Prefilled Humidifier Becton Dickinson Vacutainer Systems Pre-Analytic
Device Description	The Sterile Water for Inhalation Flex Bag USP is a flexible plastic bag with a single port at the base and is pre-filled with sterile water Tubular feed sets connect the sterile water bags to unfilled humidifier chambers The humidifier chamber is then filled with sterile water from the sterile water bags via gravity

Intended Use

The Sterile Water for Inhalation Flex Bag USP bag is intended to provide a supply of sterile water to unfilled respiratory humidifier chambers It is intended to be used in institutional and non institutional care settings

Substantial equivalence

The Sterile Water for Inhalation Flex Bag USP bag is comparable to the predicate devices in so far as it is a supply of sterile water for inhalation and is used in conjunction with a humidification system

The Cardinal Health Sterile Water for Inhalation Flex Bag has the following similarities to those which previously received 510(k) concurrence

- the same basic intended use (supply of sterile water for inhalation)
- BTT Classification
- manufactured and packaged utilizing same basic processes (sterile water for inhalation USP in a disposable plastic container)
- sterile water end use is in conjunction with humidification systems

The Cardinal Health Sterile Water for Inhalation Flex Bag described in this submission is in our opinion is substantially equivalent to the predicate device(s) disclosed

Summary of Testing Verification and Validation

Verification and Validation Testing demonstrates that the Cardinal Health Sterile Water for Inhalation Flex Bag meets its intended performance requirements at all levels and that this device is substantially equivalent to medical devices currently legally marketed in the United States

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Cardinal Health, Incorporated
C/O Mr. Ned Devine
Responsible Third Party Official
Underwriters Laboratories Incorporated
333 Pfingsten Road
Northbrook, Illinois 60062-2096

NOV 1 8 2009

Re: K090915
Trade/Device Name: Sterile Water for Inhalation Flex Bag USP
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT
Dated: November 6, 2009
Received: November 9, 2009

Dear Mr. Devine:

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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

Susan Runner, D.D.S., M.A.
Acting 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) K090915

Device Name **Sterile Water for Inhalation Flex Bag USP**

Indications for Use

The Sterile Water for Inhalation Flex Bag USP is intended to provide a supply of sterile water to unfilled respiratory humidifier chambers It is intended to be used in institutional and non institutional care settings

Prescription Use XX (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)

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

510(k) Number: K090915