K123211

510(k) Summary
A5 Anesthesia Delivery System

FEB 14 2013

This 510(k) Summary is provided in accordance with the requirements of 21 CFR 807.92.

Date: November 9, 2012

Submitter:
Mindray DS USA, Inc.
800 MacArthur Blvd.
Mahwah, NJ 07430
Contact: Russell Olsen Vice President,
Quality and Regulatory Affairs
Telephone: 201-995-8391
Facsimile: 201-995-8605

Device Trade Name: A5 Anesthesia Delivery System

Common Name: Gas Machine, Anesthesia Delivery

Device Classification:
Primary: §868.5160- BSZ Gas Machine, Anesthesia

Secondary:
§868.1400 – CCK - Carbon Dioxide Gas Analyzer
§868.1500 – NHO/CBQ/NHQ/NHP - Enflurane gas analyzer
§868.1620 – CBS - Halothane Gas Analyzer
§868.1700 – CBR - Nitrous Oxide Gas Analyzer
§868.1720 – CCL- Oxygen Gas Analyzer

Predicate Devices: AS3700 Anesthesia Delivery System / Mindray DS USA, Inc. – **K102471**
Beneview T-Series Patient Monitor / Shenzhen Mindray Biomedical Electronics C., Ltd. - **K092449**

Device description: The A5 Anesthesia Delivery System is a device used to administer to a patient, continuously or intermittently, a general inhalation anesthetic and to maintain a patient's ventilation.

Indications for Use:

The A5 Anesthesia Delivery System is a device used to administer to a patient, continuously or intermittently, a general inhalation anesthetic and to maintain a patient's ventilation.

The A5 is intended for use by licensed clinicians, for patients requiring anesthesia within a health care facility, and can be used in adult and pediatric populations.

Technological Comparison to Predicate Devices:

The A5 is equivalent to the predicate AS3700 (K102471) device respecting indications for use basic operation and performance specifications and energy supply. Both devices are used to administer a general inhalation anesthetic and to maintain a patient's ventilation and intended for use in adult and pediatric populations.

The A5 and the predicate AS3700 support manual and automatic ventilation modes. Automatic ventilation modes include VCV, PCV, PCV- VG, SIMV-PC, SIMV- PC and PS.

The A5 has been updated to incorporate respiratory gas monitoring for measuring a patient's anesthetic and respiratory gases. The anesthetic gas monitoring module utilized by the A5 is equivalent to the module utilized in the predicate Beneview T-Series Patient Monitor (K092449). Gases measured include CO_2, Desflurane, Isoflurane, Sevoflurane Halothane and Enflurane.

The A5 also incorporates material color changes and non-significant component changes relative to the AS3700.

Summary of Performance Testing:

The A5 has been tested and found to be in compliance with recognized safety, performance and electromagnetic compatibility standards.

A risk analysis has been developed to identify potential hazards and documents the mitigation of the hazards. The device's software has been verified and validated in accordance with the appropriate test requirements.

The A5 has been evaluated by end-users and found to meets performed within its intended use and met their specific needs.

The A5 has been tested and found to be in compliance with the following safety, performance and electromagnetic compatibility standards:

- IEC 60601-1:1988+A1:1991+A2:1995
- IEC 60601-1-2:2007
- IEC 60601-1-4:2000
- IEC 60601-1-8:2006
- IEC 60601-2-13:2003
- IEC 62304: 2006
- IEC 62366:2007
- ISO10993-1: 2009
- ISO 14971:2007
- ISO 15223-1:2012
- ISO 5356-1:2004
- ISO 21647:2004
- CGA V-1:2005
- CGA V-5:2008
- ASTM F1101-90:2003
- ISO10993-5:2009
- ISO10993-10:2002 +A1:2006

Conclusion:

Based on similarities in intended use and technological characteristics, results of performance and validation/verification testing, the A5 Anesthesia Delivery System is considered substantially equivalent to the predicate devices.

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

February 14, 2013

Mr. Russell Olsen
Vice President, Quality and Regulatory Affairs
Mindray DS USA, Incorporated
800 MacArthur Boulevard
MAHWAH NJ 07430

Re: K123211
Trade/Device Name: A5 Anesthesia Delivery System
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas Machine for Anesthesia or Analgesia
Regulatory Class: II
Product Code: BSZ, CCK, NHO, CBQ, NHQ, NHP, CBS, CBR, CCL
Dated: January 9, 2013
Received: January 15, 2013

Dear Mr. Olsen:

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 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,

Kwame O. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
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): K123211

Device Name: **A5 Anesthesia Delivery System**

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

Albert E. Moyal -S for LS

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

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