NOV - 4 2005

K050883

510(k) Summary

This 510(k) summary of safety and effectiveness is provided in accordance with 21 CFR 807.92.

Date of preparation: April 5, 2005

Sponsor

Safer Sleep LLC
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P.O. Box 331015
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Contact

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Phone: 425-861-8262
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Device identification

Proprietary name: SAFERsleep System
Classification name: accessory to an anesthesia gas machine
CFR 868.5160
Product code: BSZ

Substantial Equivalence

The SAFERsleep System is substantially equivalent to the Philips Compurecord Peri-Operative Anesthesiology Information System Software (K030939).

Both systems are software application programs that run on Windows-based personal computers. Both systems are intended for use by anesthesiologists for the tracking and record keeping of anesthesia procedures including the administration of drugs. Both systems can connect electronically to patient monitors that are used during the anesthesia procedure.

Device description

The SAFERsleep System is a medical device with two primary functions: to aggregate and report data on the events, anesthesia drugs, physiological parameters, and physiological reactions related to a patient undergoing anesthesia as well as to provide a visual and auditory feedback system on the anesthesia drugs selected to be administered. The visual and auditory feedback system reinforces the existing process of checking these drugs prior to administration.

Users of the SAFERsleep System will benefit from the visual and auditory feedback of the SAFERsleep System by swiping a bar-coded syringe across the SAFERsleep System bar-code scanner prior to administering anesthetic

medication. In addition, the identity of the scanned anesthetic medication will be recorded automatically and integrated into an automated anesthesia record. The SAFERsleep System will visibly flash on a computer screen the name of the drug, the international color code for the drug, and simultaneously state the drug name over the sound system of the host PC. This functionality is designed to assist anesthetic practitioners in reducing drug administration error.

Data is input to the SAFERsleep System directly from anesthetic monitors, which are connected to the patient. Additional input mechanisms have been provided (a.) to enable data input from other anesthesia equipment (for example, consciousness monitors) and (b.) to enable user entry of anesthetic drugs, events, patient data, administrative data, other clinical data and the use of specific items of equipment (such as endotracheal tubes or intravenous lines, for example). The aggregation of data from these various sources enables the formation of an automated anesthesia record and reduces the burden of manual recording keeping by the anesthetist.

510(k) Summary

This 510(k) summary of safety and effectiveness is provided in accordance with 21 CFR 807.92.

Date of preparation: October 25, 2005

Sponsor

Safer Sleep LLC
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Contact

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Drug & Device Development Co.
Phone: 425-861-8262
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Device identification

Proprietary name: SAFERsleep System
Classification name: accessory to an anesthesia gas machine
CFR 868.5160
Product code: BSZ

Indications for Use

The SAFERsleep System is a software-based product intended for use by an anesthetist to assist in the safe administration and record keeping of drugs used during an anesthetic procedure.

The SAFERsleep System provides an integrated method of information collection and documentation on drugs administered and concurrent anesthetic monitor data. The system also includes ease of use features to reduce the possibility of errors in drug administration.

Substantial Equivalence

The SAFERsleep System is substantially equivalent to the Philips Compurecord Peri-Operative Anesthesiology Information System Software (K030939).

Both systems are software application programs that run on Windows-based personal computers. Both systems are intended for use by anesthesiologists for the tracking and record keeping of anesthesia procedures including the administration of drugs. Both systems can connect electronically to patient monitors that are used during the anesthesia procedure.

In addition, the bar code capability of the SAFERsleep System has a predicate basis in the Medley System with Bar Code Module (K041241), manufactured by Alaris Medical Systems. In both systems, the bar code feature is intended for use as a means to input data on medication and thereby help verify drug identity.

Device description

The SAFERsleep System is a medical device with two primary functions: to aggregate and report data on the events, anesthesia drugs, physiological parameters, and physiological reactions related to a patient undergoing anesthesia as well as to provide a visual and auditory feedback system on the anesthesia drugs selected to be administered. The visual and auditory feedback system reinforces the existing process of checking these drugs prior to administration.

Users of the SAFERsleep System will benefit from the visual and auditory feedback of the SAFERsleep System by swiping a bar-coded syringe across the SAFERsleep System bar-code scanner prior to administering anesthetic medication. In addition, the identity of the scanned anesthetic medication will be recorded automatically and integrated into an automated anesthesia record. The SAFERsleep System will visibly flash on a computer screen the name of the drug, the international color code for the drug, and simultaneously state the drug name over the sound system of the host PC. This functionality is designed to assist anesthetic practitioners in reducing drug administration error.

Data is input to the SAFERsleep System directly from anesthetic monitors, which are connected to the patient. Additional input mechanisms have been provided (a.) to enable data input from other anesthesia equipment (for example, consciousness monitors) and (b.) to enable user entry of anesthetic drugs, events, patient data, administrative data, other clinical data and the use of specific items of equipment (such as endotracheal tubes or intravenous lines, for example). The aggregation of data from these various sources enables the formation of an automated anesthesia record and reduces the burden of manual recording keeping by the anesthetist.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 4 2005

Safer Sleep, LLC
C/O Mr. Steven Chernoff
Vice President
Drug & Device Development Company
P.O. Box 3515
Redmond, Washington 98073-3515

Re: K050883
Trade/Device Name: SAFERsleep System
Regulation Number: 868.5160
Regulation Name: Gas Machine for Anesthesia or Analgesia
Regulatory Class: II
Product Code: BSZ
Dated: October 26, 2005
Received: October 27, 2005

Dear Mr. Chernoff:

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): K050883

Device Name: SAFERsleep System

Indication for Use:

The SAFERsleep System is a software-based product intended for use by an anesthetist to assist in the safe administration and record keeping of drugs used during an anesthetic procedure.

The SAFERsleep System provides an integrated method of information collection and documentation on drugs administered and concurrent anesthetic monitor data. The system also includes ease of use features to reduce the possibility of errors in drug administration.

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 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: K050883