MAR 2 8 2012

Dräger

Premarket Notification 510(k) summary
As required per 807.92

General Company Information

Submitters Name and Address: Dräger Medical GmbH
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Contact Person:

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Alternate: Mrs. Joyce Kilroy, Draeger Medical Systems, Inc., 3135 Quarry Road, Telford, PA 18969-1042
Phone +1 (215) 660-2626,
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Versions :

Initial Version :	2010-10-08
Change 1 for submission:	2012-03-28

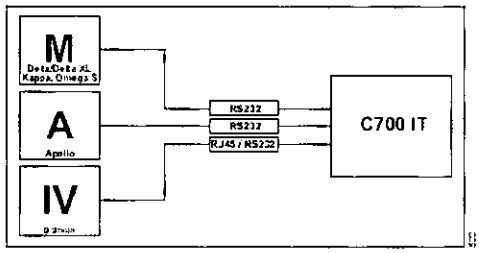
Device Name

Common Name:	Software, Information system, anaesthesia
Legally Marketed Device Identification (Trade name):	SmartPilot View
Regulation Number	868.5160
Regulation Description	Gas machine for anesthesia
Regulation Medical Specialty	Anesthesiology

Product Code	BSZ
Class	2
510(k) Number (if known):	K103035

Device description:

The current version of the SmartPilot View is receiving data from a dedicated anesthesia workstation or combination of workstation and other devices.



A Anesthesia workstation
M Monitor
IV IV pumps

The Software SmartPilot View runs on a dedicated patient vincinity workstation (Draeger C700 for IT) with the installed Infinity Explorer Software.
The data is taken from dedicated anesthesia workstation **A** (Draeger Primus US "Apollo") or combination of the workstation and other devices like **IV** Pumps (B.Braun Perfusor Space pump) and patient monitors **M** (Draeger Delta/Delta XL, Kappa, Omega S).

The software visualizes the drug effect based on pharmacokinetic models and the drug interaction based on pharmacodynamic models known from scientific literature.

The software visualizes the synergetic and additive drug effect on a screen in a specially developed 2D pharmacodynamic diagram. Furthermore a new pharmacodynamic parameter (NSRI) is calculated based on the synergetic drug effects.

The software monitors and calculates data for the use during the anesthesia case. The software also logs data during the anesthesia case for a retrospective analysis.

Supported drugs:

Intravenous hypnotics
- Propofol

Volatile hypnotics
- Isoflurane
- Sevoflurane
- Desflurane
- Enflurane

Intravenous opioids
- Fentanyl
- Remifentanil
- Sufentanil
- Alfentanil

Intravenous muscle relaxants
- Pancuronium
- Rocuronium

Parameters provided by the basic device (monitor and anaesthesia machine)
- Heart rate HR in 1/min
- Mean non-invasive blood pressure NIBP M or mean arterial pressure ART M in mmHg or kPa.
- End-expiratory CO2 concentration etCO2 in mmHg, Vol.% or kPa.
- Bispectral index BIS
- BIS signal quality index SQI in %

Statement of Indications / Intended Use:

The SmartPilot View is software which monitors and logs the dosage of intravenous and volatile drugs administered to a human being. Additionally, SmartPilot View displays pharmacokinetic, pharmacodynamic (PK/PD) and interactive PD modeling information.

Smart Pilot provides the health care professional with theoretical information about the modeled effect of supported anesthesia pharmaceuticals delivered to the patient.

The SmartPilot View is software for use by health care professionals trained in the application of general anaesthesia.

The SmartPilot View is intended for use with data from adults only. The demographic ranges for these patient data are as follows:

Height 59 in to 79 in (150 cm to 200 cm)
Weight 88 lb to 309 lb (40 kg to 140 kg)
Age 18 to 90 years

Substantial Equivalence (identification of the legally marketed Predicate):

With respect to the pharmacokinetic and pharmacodynamic calculation and display of data the Smart Pilot View is equivalent to the Navigator Applications Suite (K071097, K081941, K083098, K102389) from GE Healthcare Finland Oy.
The display of the monitoring data is equivalent to the Software Infinity Explorer (K013515, K022889, K030615, K040945, K060254) from Draeger Medical Systems, Inc..

Assessment of non-clinical testing:

The SmartPilot View has been tested according to its specifications, including software validation.
The following standards and guidelines were used to support the safe use of the Software:

ISO 14971 :2007	Medical devices - Application of risk management to medical devices
IEC 62304 :2006	Medical device software - Software life-cycle processes
FDA CDRH Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (Document issued on: May 11, 2005)	

Clinical performance data:

Not applicable

Biocompatibility:

Not applicable

Sterilization:

Not applicable

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Draeger Medical GmbH
C/O Ms. Royce Kilroy
Vice President
Draeger Medical System, Incorporated
3135 Quarry Road
Telford, Pennsylvania 18969

MAR 2 8 2012

Re: K103035
Trade/Device Name: SmartPilot View
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas Machine for Anesthesia or Analgesia
Regulatory Class: II
Product Code: BSZ
Dated: March 22, 2012
Received: March 23, 2012

Dear Ms. Kilroy:

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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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 Statement

510(k) Number (if known): K103035

Device Name: SmartPilot View

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

510(k) Number: K103035

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)