K102968

Traditional 510(k)
Infinity CNAP SmartPod

FEB 18 2011

Dräger

510(k) SUMMARY of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990, 21 CFR §807.87, 21 CFR §807.92, Format for Traditional and Abbreviated 510(k).

1. Name of Submitter, Contact Person and Date Summary Prepared:

Name:	Draeger Medical Systems, Inc.
Address:	6 Tech Drive Andover, MA 01810-2434
Phone:	267-885-9989
Fax:	215-721-5424
Official Contact:	Joyce Kilroy
Date of Preparation:	September 31, 2010

2. Device Trade Name and Common Name:

Trade Name:	Infinity CNAP SmartPod
Common/Usual Name:	System, Measurement, Blood-Pressure, Non-Invasive
Classification:	21 CFR 870.1130

3.

Product Code:	DXN
Device Class:	Class II

4. Legally Marketed Equivalent (Predicate) Device Names:

Substantial equivalence is claimed to the CNSystems CNAP Monitor 500i under submission # K082599

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5. Performance Standards:

None.

6. Description of the Device:

The Draeger Infinity CNAP SmartPod technology was developed with CNSystems and is similar to their CNAP Monitor System 500i (K082599).

The Draeger Infinity CNAP SmartPod connects to an Infinity modular monitor (K070566) for the display and alarming of continuous non-invasive blood pressures: CNAP-S (Systolic), CNAP-D (Diastolic), and CNAP-M (Mean). CNAP parameter alarms can be set via the alarm limits menu of the monitor.

The Infinity CNAP SmartPod is a device for continuous non-invasive blood pressure monitoring. The device measures continuous and oscillometric blood pressure as well as pulse rate. CNAP is a joint solution, where absolute blood pressure values are coming from an integrated OEM Oscillometric blood pressure device and beat-to-beat changes as well as waveform are measured with the CNAP finger sensor. Finger-BP is automatically calibrated to absolute NIBP-values. Immediately after a NIBP, the CNAP computer puts systolic and diastolic finger BP on the same level as NIBP values. NIBP calibration can be obtained ipsilateral as well as contralateral to the CNAP-cuff.

The Infinity CNAP SmartPod works by utilizing integrated photo-plethysmograph (light-emitting diode and detector) sensors. These sensors are located in an occluding Dual Finger cuff placed around the patient's fingers. While the cuff is maintained at the mean arterial pressure, the sensor detects changes in blood volume based on the amount of light transmitted through the finger. With the cuff inflated to mean arterial pressure, the signal output varies directly with any change in blood volume. Systemic blood pressure can then be calculated beat to beat, and a correlation with arterial pressure obtained via a standard oscillometric measurement from the patient monitor. The resulting derived arterial values and pressure waveforms are then displayed on the monitor.

7. Intended Use of the Device:

The Infinity CNAP SmartPod is indicated for the continuous, non-invasive monitoring of arterial blood pressure in adults by medical professionals. The Infinity CNAP SmartPod is intended for use with the Infinity Modular patient monitors of the Delta series (Delta, Delta XL, Kappa, SC7000, SC8000, SC9000XL). Derived arterial values and pressure waveforms are displayed when a pod is connected to one of the previously identified patient monitors.

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The Infinity CNAP SmartPod supports the following parameters:

Continuous and oscillometric blood pressure
Pulse rate
CNAP-S (systolic pressure)
CNAP-D (diastolic pressure)
CNAP-M (mean pressure)

The Infinity CNAP Smartpod performance may be affected in situations where the flow of blood to the finger is severely inhibited or in the presence of pathologically increased stiffness of the finger arteries. Included as examples:

- Cases of severe shock or hypothermia
- Severe arteriosclerosis of the upper extremities
- Primary or secondary Raynaud's syndrome and related diseases
- Endarteritis obliterans
- Collagenosis affecting peripheral arteries

The Infinity CNAP SmartPod is not intended for use on patients with vascular implants at the site of measurement.
The Infinity CNAP SmartPod is not compatible for use in a MRI magnetic field.

8. Comparison of Technological Characteristics with Predicate Devices:

This device employs the same functional technology as the predicate device.

9. Discussion of Non-clinical Studies:

The Infinity CNAP SmartPod was tested in accordance with the applicable standards and internal design control procedures and was determined to be as safe and effective for its intended use as the predicate device. Testing performed indicate that the software modifications described in this submission are as safe and effective as previous versions and have not altered the fundamental technology of the device(s).

10. Biocompatibility:

All relevant components are shown to be biocompatible.

11. Sterilization:

Not Applicable

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12. Standards and Guidance:

Electrical Safety:	IEC 60601-1: Medical electrical equipment general requirements for safety and essential performance
Guidance Documents:	Non-Invasive Blood Pressure (NIBP) Monitor Guidance – released on March 10, 1997

13. Conclusion:

The results of testing demonstrate that the device is safe and effective and substantially equivalent to its predicate device.

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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 Systems, Inc.
c/o Ms. Joyce Kilroy
Vice President, Process, Quality and Regulatory
6 Tech Drive
Andover, MA 01810

FEB 18 2011

Re: K102968
Trade/Device Name: Draeger Infinity CNAP SmartPod
Regulatory Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (Two)
Product Code: DXN
Dated: February 14, 2011
Received: February 14, 2011

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.

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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K102968

Device Name: Infinity CNAP SmartPod

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(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K102968

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Prescription Use_✔_ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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