K081823

510(k) Summary

MAY 18 2009

GENERAL INFORMATION

5.1 Type of Submission

Traditional 510(k) Submission

Submission date: 06/03/2008

5.2 Submitter

Name: VIASYS Healthcare GmbH (owned by Cardinal Health)

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Contact person in Germany:

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(US Agent)	**Yvette Lloyd**
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5.3 Establishment Registration Number

9615102

5.4 Common Name or Classification Name

Plethysmograph, Pressure (CFR 868.1750, Product Code CCM)
Predictive pulmonary-function value calculator (CFR 868.1890 Product Code BTY)

5.5 Trade Name

MasterScreen Paed – Baby Body	→ complete device
MasterScreen Baby Body	→ device without adult handle/shutter
MasterScreen Paed	→ device without baby body cabin

5.6 Classification

This is a Class II device

5.7 Classification Panel

73 Anesthesiology Part 868

5.8 Reason for Premarket Notification

New options to an existing VIASYS device.
(Squeeze measurement for babies and lung function measurements for children)

5.9 Legally predicate marketed devices

MasterScreen Paed - Baby Body
K023796 / Code CCM

MasterScreen PFT Body
K072061 / Code JEH

IPL (Infant Pulmonary Laboratory) or Collins Infant Plethysmograph
K011344 / Code BZC, BZG, CCM

5.10 Predicate Device Company

VIASYS HEALTHCARE GmbH
(since July 01, 2007 owned by Cardinal Health – owner no. 9028292)

Collins Medical, Inc. (owned by nSpire Health Inc. – owner no. 9105240)

5.11 Device Description

MasterScreen Paed – Baby Body is a pediatrics device providing following characteristics:

- Mains operation
- Trolley for device and Baby Body box
- Personal Computer System
- Graphic user interface Windows XP Professional
- Powerful database for storing patient- and test data
- Tidal Breathing Analysis
- Baby-Body Plethysmography
- Baby Resistance / Compliance
- Rapid Thoracic Compression (RTC)
- Raised Volume – Rapid Thoracic Compression (RV-RTC)
- Spirometry / Flow Volume / MVV for children and adolescents
- Airway Resistance (R Occlusion) for children and adolescents
- P.01 / PImax / PEmax for children and adolescents

5.12 Intended Use Statement

The MasterScreen Paed – Baby Body is a lung function measurement system for paediatric use. It is intended to be used under the direction of a physician. The MasterScreen Paed - Baby Body may be used in the clinic, doctor's office, or hospital. Patient populations that may benefit from the use of this device include newborns (neonate), infants, children and adolescent.

The lung function measurements including RTC and RV-RTC can be performed in term neonates (weight 3kg) up to toddlers (weight 13kg). The digital adult pneumotach with shutter feature is for use with children and adolescent from 4 up to 21 years. The device is AC powered from 115V-240V / 50-60Hz wall outlet.

5.13 Required Components

Desktop PC
Monitor
Trolley with power supply
Pneumotach handle / Shutter
Baby Body box
Accessories
User Manual

5.14 Summary Table of Comparision

Comparison of MS Paed – Baby Body with the new features to MS Paed – Baby Body with 510(k) # K023796		
	MasterScreen Paed – Baby Body with 510(k) # K023796	**MasterScreen Paed – Baby Body with new features**
Intended Use	The MS PAED – BABY BODY is a neonatal lung function measurement system that utilizes a bodyplethysmograph. It is intended to be used under the direction of a physician. MS PAED – BABY BODY may be used in the clinic, doctors office, or hospital. Patient population that may benefit from the use of this device include only babies and premature infants. The MS PAED – BABY BODY, or any of the accessories supplied with it, is not to be used, alone or in combination, as a life support device, a life support system, or as a critical component in a life support device or life support system.	The MasterScreen Paed – Baby Body is a lung function measurement system for paediatric use. It is intended to be used under the direction of a physician. The MasterScreen Paed - Baby Body may be used in the clinic, doctor's office, or hospital. Patient populations that may benefit from the use of this device include newborns (neonate), infants, children and adolescent. The lung function measure-ments including RTC and RV-RTC can be performed in term neonates (weight 3kg) up to toddlers (weight 13kg). The digital adult pneumotach with shutter feature is for use with children and adolescent from 4 up to 21 years. The device is AC powered from 115V-240V / 50-60Hz wall outlet.
Patient population	• Babies • Premature Infants from 4 to 40 lbs	• Newborns (Neonate) • Infants from 4 to 40 lbs • Children • Adolescent up to 21 year
Performance (Measurements)	• Tital Breathing Analysis • Baby Bodyplethysmo-graphy [Functional Residual (FRC) and Airway Resistance (Raw) – Conductance (Gaw)] • Resistance Single Occlusion Technique (SOT) and Double Occlusion Technique (DOT) • Compliance	**Identical**

Software	• JLAB Version 4.5	• JLAB Version 4.6
Device Specification	**PT Paed S** • Flow range 0 to +/- 1500 ml/s • Flow resolution 1 ml/s • Flow accuracy +/- 3% / +/- 4 ml/s • Volume range +/- 3000 ml • Volume resolution 0,1 ml • Deadspace 1,7 ml **Mouth pressure** • Range +/- 5 kPa • Resolution 0,003 kPa • Accuracy +/- 2% **Shutter** • Balloon material Latex • Balloon pressure 0,9 bar • Balloon volume 0,7 ml **Baby Body (Cabin)** • Length – weight – height 127cm - 71cm - 128cm • Box volume 98 liters • Box sensor +/- 80 ml at 1000 hPa • Resolution 0,04 ml • Accuracy +/- 1%	**Identical**
Accessories	• Manual Calibration Syringe 100 ml • Paediatric-PT XS • Paediatric-PT S • Screen small for paediatric • Screen large for paediatric • Anesthetic mask type "Silikomed" size 0 • Anesthetic mask type "Silikomed" size 1	**Identical**

Comparison of MS Paed – Baby Body with the new features to MasterScreen PFT Body with 510(k) # K072061		
	MasterScreen PFT Body with 510(k) # K072061	**MasterScreen Paed – Baby Body with new features**
Performance (New measure-ments)	• Spirometry • MVV • Flow Volume • R Occlusion • Respiratory Muscle Strength and Respiratory Drive (P.01 / PImax / PEmax)	**Identical**
Device Specification	**PT Adult (MS-Paed only)** • Flow range 0 to +/- 20 l/s • Flow resolution 0,01 l/s • Flow accuracy +/- 2% / 0,2 to 12 l/s • Volume range +/- 20 l • Volume resolution 0,001 l • Dead space 0,07 l	**Identical**

Comparison of MS Paed – Baby Body with the new features to Infant Plethysmograph (IPL) with 510(k) # K011344		
	Infant Plethysmograph (IPL) with 510(k) # K011344	**MasterScreen Paed – Baby Body with new features**
Performance (New measure-ments)	• Rapid Thoracic Compression (RTC) • Raised Volume Rapid Thoracic Compression (RV-RTC)	• Rapid Thoracic Compression (RTC) • Raised Volume Rapid Thoracic Compression (RV-RTC)

5.15 Summary of Device Testing

The following practices were followed and monitored for development of the MasterScreen Paed – Baby Body / MasterScreen Baby Body and MasterScreen Paed:

The new options for the above devices were developed in accordance with the VIASYS development standard operating procedures (000490 06 – Design Control).

The risk analysis method used to assess the impact of the MasterScreen Paed – Baby Body with the new options Squeeze and the adult handle for children was a Failure Modes and Effects Analysis (FMEA).

Safety test procedures demonstrate satisfaction of all safety requirements and mitigation of all identified hazards.

The software was developed according to the IEC 601-1-4 Standard.

The EMC testing was performed according EN 60601-2.

5.16 Conclusions

Based on the above, VIASYS HEALTHCARE GMBH concludes that the MasterScreen Paed – Baby Body is substantially equivalent to legally marketed predicate devices and is safe and effective for its intended use, and performs at least as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 18 2009

Mr. Thomas Rust
VIASYS Healthcare GmbH
Leibnizstrasse 7
D-97204 Hoechberg
GERMANY

Re: K081823
Trade/Device Name: MasterScreen Paed – Baby Body
MasterScreen Baby Body
MasterScreen Paed
Regulation Number: 21 CFR 868.1880
Regulation Name: Pulmonary-Function Data Calculator
Regulatory Class: II
Product Code: BZC, CCM
Dated: May 13, 2009
Received: May 15, 2009

Dear Mr. Rust:

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 contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner

Susan Runner, D.D.S., MA
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): K081823

Device Name: MasterScreen Paed - Baby Body
MasterScreen Baby Body
MasterScreen Paed

Indications for Use:

The MasterScreen Paed – Baby Body is a lung function measurement system for paediatric use. It is intended to be used under the direction of a physician. The MasterScreen Paed - Baby Body may be used in the clinic, doctor's office, or hospital. Patient populations that may benefit from the use of this device include newborns (neonate), infants, children and adolescent.

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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: K081823