510(k) SUMMARY

K080734

GENERAL INFORMATION

JUN 2 6 2008

1. Applicant

Date: May 05th, 2008

Name: VIASYS Healthcare GmbH (owned by **Cardinal Health**)

Address: Leibnizstrasse 7
D-97204 Hoechberg
Germany

Contact person in Germany:

(Official Correspondent)	**Thomas Rust**
Address	VIASYS Healthcare GmbH Leibnizstrasse 7, 97204 Hoechberg Germany
Phone:	+49 931 4972 - 383
FAX:	+49 931 4972 - 62383
E-mail	Thomas.Rust@viasyshc.com
or at:	Thomas.Rust@cardinalhealth.com

Contact person in USA:

(US Agent)	**Yvette Lloyd**
Address	Cardinal Health 22745 Savi Ranch Parkway Yorba Linda, CA 92887
Phone/Fax:	(714) - 919 - 3247
E-mail	Yvette.Lloyd@cardinalhealth.com

2. Trade Name

FlowScreen
FlowScreen ECG
FlowScreen CT

3. Classification Name

Pulmonary calculator (21 CFR 868.1890, Product Code BTY)
Electrocardiograph (21 CFR 870.2340, Product Code DPS)

4. Establishment Registration Number

9615102

5. Facility Address

VIASYS Healthcare GmbH
Leibnizstrasse 7
D-97204 Hoechberg
Germany

6. Section 513 Device Classification

6.1 Classification

This is a Class II device

6.2 Classification Panel

Panel 73, Anesthesiology
Code BTY
Panel 74, Circular System Devices, ECG
Code DPS

7. Reason for Premarket Notification

New option for FlowScreen K062011
(Combination of two VIASYS devices, K062011 + K070614)

8. Predicate Devices Descriptions

8.1 Name

a) FlowScreen
b) CorScreen

8.2 Predicate Device Company

Viasys Healthcare GmbH

8.3 Predicate Device 510(k)#

a) K062011
b) K070614

9. Device Description

FlowScreen is an active medical device providing following characteristics:

Mains operation
Colour LCD display for user interface
Alphanumerical keyboard
Colour ink-printer for printout of reports in US-letter and DIN A4 size
Patient information and measurements are stored in an internal database
Data can be stored on an SD memory card

a) pulmonary functions

- Measurement with ultrasonic handle or pneumotach handle
- Slow spirometry (VCin, VCex, VCmax, ERV, IC, VT, IRV, MV, BF, TI, TE, ...)
- Forced spirometry (FVCin, FVC, FEV1, PEF, FEV1/FVC, FEF 50, FEF 75, PIF, ...)
- Flow-Volume and Volume-Time Loop, pre/post tests
- MVV measurement
- Trending capabilities
- Patient Incentive animations
- Interpretation modules

K080734

b) ECG functions

- Simultaneous acquisition of the 12 standard leads
- Storage of 10 seconds of acquired ECG signal
- Digital filters for base-line drift and mains interference suppression
- Interpretation program Hanover ECG System (HES) providing the following additional information:
  - Representatives templates of each lead including markers on fiducial points
  - Summary of mean measurements
  - Rhythm Analysis statements
  - Signal noise detection and information
  - Specific findings on QRS complex
  - Conduction statements
  - QRS T diagnostic statements
  - Arrhythmia monitoring detection
  - Heart Rate Variability

10. Intended Use Statement

The FlowScreen / FlowScreen ECG is a diagnostic system for recording and assessing inspiratory and expiratory pulmonary function (spirometry).
In addition it is intended for measuring a 3/6- or 12-channel surface electrocardiogram (ECG) of a patient. The acquired ECG can be recorded and displayed on a screen or printed on paper. 12-channel ECGs are analysed automatically and suggestions for the interpretation of the 12-channel ECG can be made by the software.
FlowScreen / FlowScreen ECG can be used for non interpretive applications for patients with an age of 4 years and older and a weight of 20 kg or higher. FlowScreen / FlowScreen ECG is intended for use in routine ECG recording by trained physicians in the office or hospital. FlowScreen / FlowScreen ECG is not intended for intracardial use. Automatic interpretation of the ECG is not possible for pediatric patients with an age below 16 years and for pacemaker patients.

FlowScreen CT (Clinical Trial version) incorporates the identical measurements, but individual access rights are defined for different user roles (e.g. Investigator, doctor, study nurse, trainer and service personnel).

The interpretation software is intended to support the physician in evaluation the ECG in terms of morphology and rhythm.
A qualified physician has to reassess all FlowScreen measurements. An interpretation by FlowScreen is only significant if it is considered in connection with other clinical findings. ECG interpretation statements made by the FlowScreen represent partial qualitative and quantitative information on the patient's cardiovascular condition and no therapy or drugs can be administered based solely on the interpretation statements.
The FlowScreen is powered from 100 - 240V / 50 - 60Hz wall outlets. No energy is transferred to the patient.

Federal U.S. law restricts this device to sale by or on the order of a physician.

11. Required Components

FlowScreen – monitor
Ultrasonic handle or pneumotach handle
ECG-amplifier
Disposable ECG-electrodes
User manual

K080734

12. Summary table of comparison

Pulmonary Function				
#	**Parameter**	**New Device: FlowScreen**	**Predicate Device: FlowScreen K062011**	**Result**
1	Intended Use	Diagnostic Spirometry (VCin, VCex, etc.)	Diagnostic Spirometry (VCin, VCex, etc.)	identical
2	Patient population	To be used as a screening device to determine whether or not a patient requires further diagnosis for pulmonary function disorders	To be used as a screening device to determine whether or not a patient requires further diagnosis for pulmonary function disorders	identical
3	Performance	Slow Spiormetry Forced Spiormetry Flow-Volume MVV Pre/Post Tests Trending capabilities Interpretation modules	Slow Spiormetry Forced Spiormetry Flow-Volume MVV Pre/Post Tests Trending capabilities Interpretation modules	identical
4	Patient user interface	Ultrasonic handle or pneumotach handle	Ultrasonic handle or pneumotach handle	identical
5	Material of patient user interface	Pneumotach handle: Pneumotach (Ultem 1010R, handle (Romira ABS 1001 FRV0), mouthpiece (Polypropylene RG835MO) Ultrasonic handle: handle (Luran S778 TE), mouthpiece (HDPE Eraclene MS 80U)	Pneumotach handle: Pneumotach (Ultem 1010R, handle (Romira ABS 1001 FRV0), mouthpiece (Polypropylene RG835MO) Ultrasonic handle: handle (Luran S778 TE), mouthpiece (HDPE Eraclene MS 80U)	identical
6	Patient contacting accessories	Mouthpiece Nose clip Nose pads	Mouthpiece Nose clip Nose pads	identical
7	Material of patient contacting accessories	Nose clip: Polyacetal Nose pads: Ethylene Vinyl Acetate	Nose clip: Polyacetal Nose pads: Ethylene Vinyl Acetate	identical
8	Dimensional specification	455 x 280 x 380 (W x H x D)	455 x 280 x 380 (W x H x D)	Identical
9	Software	Data acquisition Data calculation Calc. of predicted values Data analysis Data interpretation Data storage Data output Data input	Data acquisition Data calculation Calc. of predicted values Data analysis Data interpretation Data storage Data output Data input	Identical

K080734

ECG Function				
#	**Parameter**	**New Device: FlowScreen**	**Predicate Device: CorScreen K070614**	**Result**
1	Intended Use	3/6- or 12-channel surface ECG recording device	3/6- or 12-channel surface ECG recording device	identical
2	Input dynamic range	+/- 300mV @ DC	+/- 300mV @ DC	identical
3	Frequency response Bandwidth	0,05 – 150 Hz / According to EC11 and IEC 60601-2-51	0,05 – 150 Hz / According to EC11 and IEC 60601-2-51	identical
4	A/D conversion	24 bits	24 bits	identical
5	Leads	12 Standard	12 Standard	identical
6	Paper Speed	25 50 mm/s +/-5% According to EC11	25 50 mm/s +/-5% According to EC11	identical
7	Recorder Sensitivity	5 10 20 mm/s According to EC11	5 10 20 mm/s According to EC11	identical
8	Writing System	Ink-printer US-letter and DIN-A4 size	Ink-printer US-letter and DIN-A4 size	Identical
9	Printed Channels	1/2/6/12	1/2/6/12	Identical
10	Paper	US-Letter and DIN-A4	US-Letter and DIN-A4	Identical
11	Mode of operation	Manual	Manual	Identical
12	Input/output	SD Memory card	SD Memory card	Identical
13	**Display**			
14	Size	320 x 240 pixels	320 x 240 pixels	Identical
15	No. of displayed channels	1/3/6/12	1/3/6/12	Identical
16	Trace speeds	5 10 25 50 mm/s	5 10 25 50 mm/s	Identical
17	Sensitivity	5 10 20 40 mm/mV	5 10 20 40 mm/mV	Identical

K080734

Hardware platform		
FlowScreen	**FlowScreen K062011**	**CorScreen K070614**
Power supply	Identical	Identical
Mainboard	Identical	Identical
Connector board	Identical	Identical
Interfaces	Identical	Identical
Color printer	Identical	Identical
Keyboard	Identical	Identical
Color display	Identical	Identical
Enclosure	Identical	Identical
Hardware patient user interfaces		
Patient user interface pneumotach handle	Identical	----------
Patient user interface USS-handle	Identical	----------
ECG Amplifier	----------	Identical
Accessories		
Mouthpiece	Identical	----------
Nose clip	Identical	----------
ECG electrodes	----------	Identical
Software / Firmware / Operating System		
Boot loader (u-boot)	Identical	Identical
Operating system (Linux)	Identical	Identical
Firmware:		
Base module	Identical	Identical
Spirometry module	Identical	----------
ECG module	----------	Identical

K080734

13. Summary of non-clinical performance tests

The following practices were followed and monitored for development of the FlowScreen / FlowScreen ECG / FlowScreen CT:

The risk analysis method used to assess the impact of the FlowScreen with the new option ECG was a Failure Modes and Effects Analysis (FMEA). The risk analysis and risk control document number is 651003 17.

The design validation tests that were performed as a result of this risk analysis assessment and functional specifications are documented in document "Validation test script" and "validation test log" with document number 671003 32 (Test Script), 671003 33 (Test Log), 671003 40 (Test Script Workflow ECG) and 671003 41 (Test Log Workflow ECG).

The safety test procedures demonstrate satisfaction of all safety requirements and mitigation of all identified hazards. The document numbers for the performed safety tests according IEC 60601-1 are 407.267.2 and 71320123. The document number according IEC60601-2-25 is 407.267.3.

The EMC testing was performed according EN60601-2 with the document numbers 266.182 and 267.281.

Conclusion:
Based on the above, VIASYS HEALTHCARE GMBH concludes, that FlowScreen is determined substantially equivalent to the legally marketed predicate VIASYS devices and is safe and effective for its intended use, and performs at least as well as the predicate devices. The FlowScreen / FlowScreen ECG / FlowScreen CT is a combination of FlowScreen K062011 and CorScreen K070614 on the identical hardware base.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 6 2008

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

Re: K080734
Trade/Device Name: FlowScreen
FlowScreen ECG
FlowScreen CT
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive Pulmonary Function Value Calculator
Regulatory Class: II
Product Code: BTY,DPS
Dated: May 7, 2008
Received: May 12, 2008

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.

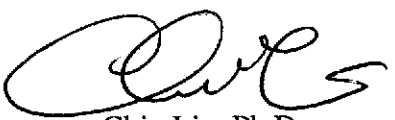
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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): K080734

Device Name: FlowScreen
FlowScreen ECG
FlowScreen CT

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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

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