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510(k) Summary

GENERAL INFORMATION

DEC 0 2 2008

5.1 Type of Submission

Traditional 510(k) Submission

Submission date: 08/26/2008

5.2 Submitter

Name: Cardinal Health Germany 234 GmbH
(formerly Viasys Healthcare GmbH)

Address: Leibnizstrasse 7
D-97204 Hoechberg
Germany

Contact person in Germany:

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Contact person in the U.S.:

(US Agent)	**Yvette Lloyd**
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Phone/Fax:	(714) - 919 - 3247
E-mail	Yvette.Lloyd@cardinalhealth.com

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5.3 Establishment Registration Number

9615102

5.4 Common Name or Classification Name

Predictive pulmonary-function value calculator (CFR 868.1890 Product Code BTY)
Electrocardiograph (CFR 870.2340, Product Code DPS)

5.5 Trade Name

MasterScope
MasterScope ECG
MasterScope CT → this is the clinical trial version

5.6 Classification

This is a Class II device

5.7 Classification Panel

73 Anesthesiology Part 868
74 Circular System Devices, ECG Part 870

5.8 Reason for Premarket Notification

New option to an existing Cardinal Health device.
(ECG option for MasterSope K071753)

5.9 Legally predicate marketed devices

MasterScope / MasterScreen Pneumo
K071753 / Code BTY

FlowScreen / FlowScreen ECG / FlowScreen CT
K080734 / Code BTY, DPS

5.10 Predicate Device Company

Cardinal Health Germany 234 GmbH
(Owned by Cardinal Health Inc. – owner no. 9028292)

5.11 Device Description

MasterScope / MasterScope ECG is an active device providing following characteristics:

Mains operation
Personal Computer System
Graphic user interface Windows XP Professional
LAB Software
Powerful database for storing patient- and test data

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Ultrasonic handle
Pneumotach handle/shutter
ECG Amplifier

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
- R Occlusion (only with pneumotach handle)
- Trending capabilities
- Patient Incentive animations
- Interpretation modules

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 fiducially 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

5.12 Intended Use Statement

Device Name: MasterScope
MasterScope ECG
MasterScope CT

Indications for Use:

The MasterScope / MasterScope ECG is intended to be used for measurement and data collection of lung function parameters. The system performs cooperation-dependent flow volume measurements. Mostly it will be used for COPD and Asthma patients.
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 the screen or printed on paper. 12-channel ECG's are analysed automatically and suggestions for the interpretation of the 12-channel ECG can be made by the software.
MasterScope / MasterScope 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. MasterScope / MasterScope ECG is intended for use in routine ECG recording by trained physicians in the office or hospital. MasterScope / MasterScope 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.

MasterScope CT (Clinical Trial version) incorporates the identical measurements. In addition it offers workflow control elements to restrict the use of the equipment (e.g. individual access rights are defined for different user roles like 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 MasterScope / MasterScope ECG measurements. An interpretation by MasterScope / MasterScope ECG is only significant if it is considered in connection with other clinical findings. ECG interpretation statements made by the MasterScope / MasterScope ECG 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 MasterScope / MasterScope ECG / MasterScope CT is powered from 100 - 240V / 50 - 60Hz wall outlets. No energy is transferred to the patient.

5.13 Required Components

Notebook
Pneumotach handle/shutter or Ultrasonic handle or/and ECG Amplifier
Accessories
User Manual

5.14 Summary Table of Comparision

Pulmonary Function Comparison		
	New Device: MasterScope with the new features	**Predicate Device: MasterScope K071753**
Intended Use	Diagnostic Spirometry (VCin, VCex, etc.)	**Identical**
Patient population	To be used as a screening device to determine whether or not a patient requires further diagnosis for pulmonary function disorders.	**Identical**
Performance (Measurements)	• Tital Spirometry (VT, VCin, ERV, ...) • Forced Spirometry • Flow-Volume (FVC, FEV1, MEF50, ...) • Maximum Voluntary Ventilation • R Occlusion (only possible with pneumotach handle) • Interpretation and quality assessment compliant with ERS/ ATS criteria	**Identical**

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Software	• Windows XP with LAB Software	**Identical**
Patient user interface	Digital handle (pressure sensor) or Digital handle (ultrasonic sensor)	**Identical**
Material of patient user interface	Pressure sensor Pneumotach: Ultem 1010R Handle (PT): Romira 1001R Ultrasonic sensor Ultrsonic handle: Luran S778TE	**Identical**
Patient contacting accessories	Nose Clip Nose Clip pads Single use mouthpiece for PT Single use mouthpiece for USS	**Identical**
Material of patient contacting accessories	Nose Clip: Polyacetal Nose Clip pads: Ethylene Vinyl Acetate Single use mouthpiece (PT): Polypropylen RG835MO Single use mouthpiece (USS): HDPE Eraclene MS 80U	**Identical**
Energy type	100 – 240V AC 50/60Hz	**Identical**

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ECG Function Comparison		
	New Device: MasterScope with the new features	**Predicate Device: FlowScreen K080734**
Intended Use	3/6- or 12-channel Surface ECG recording device	**Identical**
Application	ECG recording	**Identical**
Bandwidth	0 – 150 Hz digital	**Identical**
ECG leads	Acc. to Einthoven, Wilson, Goldberger	**Identical**
Leads	12 Standard	**Identical**
A/D Resolution	2,6 µV/bit ECG, 19 bit	**Identical**
Sampling rate per channel	1000 Hz	**Identical**
Sampling rate for pacemaker detection	4000 Hz	**Identical**
Connection to PC	USB connection	Serial connection
Power supply	5V DC via USB interface	5V DC via Serial interface
Connection to electrodes	4 mm snap connector, gold plated	**Identical**
Patient contacting accessories	• Single use electrode • Electrode cable	**Identical**
ECG Amplifier enclosure material	ABS/PC (no patient contacting part)	Santoprene TPV 281-87 MED

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5.15 Summary of Device Testing

The following practices were followed and monitored for development of the MasterScope with the new option ECG:

The new option for the above device was developed in accordance with the Cardinal Health development standard operating procedures (000490 06 – Design Control).

The risk analysis method used to assess the impact of the MasterScope with the new option ECG 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 60601-1-2.

5.16 Conclusions

Based on the above, Cardinal Health Germany 234 GmbH concludes that the MasterScope with the ECG option 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

DEC 0 2 2008

Mr. Thomas Rust
Regulatory Affairs Manager
Cardinal Health Germany 234 GmbH
Leibnizstrasse 7
Hoechberg, Bavaria
GERMANY 97204

Re: K082539
Trade/Device Name: MasterScope, MasterScope ECG, MasterScope CT
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive Pulmonary-Function Value Calculator
Regulatory Class: II
Product Code: BTY, DPS
Dated: August 26, 2008
Received: September 3, 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 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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Linda Y. Michaels m.d.

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

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Indications for Use

510(k) Number (if known):

Device Name: MasterScope
MasterScope ECG
MasterScope CT

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

Scott J. McNeil DMD

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

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