 K090486

# 510(k) Summary

## GENERAL INFORMATION

MAY - 6 2009

### 5.1 Type of Submission

Special 510(k) Submission

Submission date: 02/17/2009

### 5.2 Submitter


Name: Cardinal Health Germany 234 GmbH

Address: Leibnizstrasse 7
D-97204 Hoechberg
Germany

**Contact person in Germany:**

**Thomas Rust**
Address: Cardinal Health Germany 234 GmbH
Leibnizstrasse 7, 97204 Hoechberg
Germany
Phone: +49 931 49 72 - 383
FAX: +49 931 49 72 - 62383
E-mail Thomas.Rust@cardinalhealth.com

**Contact person in the U.S.:**
**(Official Correspondent)**

**Thomas Gutierrez**
Address Cardinal Health
22745 Savi Ranch Parkway
Yorba Linda, CA 92887
Phone / FAX: (714) - 919 – 3342
E-mail Thomas.Gutierrez@cardinalhealth.com

**5.3 Establishment Registration Number**

9615102

**5.4 Common Name or Classification Name**

Diagnostic Spirometer (CFR 868.1840, Product Code BZG)

**5.5 Trade Name**

Asthma Monitor AM1+
Asthma Monitor AM1+ BT

**5.6 Device Classification**

This is a Class II device

**5.7 Classification Panel**

73 Anesthesiology Part 868
Code BZG

**5.8 Reason for Premarket Notification**

Device modification to an existing Cardinal Health - device regarding "The New 510(k) Paradigm"

**5.9 Legally predicate marketed device**

Asthma Monitor AM2
K980676 Code BZG

**5.10 Predicate Device Company**

Cardinal Health Germany 234 GmbH

**5.11 Device Description**

The Asthma Monitor AM1+ / AM1+ BT is a medical device (peak flow meter with symptom diary) providing following characteristics:

- Handheld device
- Battery operation
- Storing capacity of 400 measurements / 2000 entries
- Measurement Parameters: PEF and FEV1
- Accuracy Flow: ± 5% or ± 20 l/min
- Accuracy Volume: ± 3% or ± 0.05 liter
- Data transmission to computer via Bluetooth and Serial (AM1+ BT)
- Data transmission to computer via Serial (AM1+)
- Flow sensor (single patient use)
- Mouthpiece (single patient use)

## 5.12 Intended Use Statement

The Asthma Monitor AM1+ / AM1+ BT from Cardinal Health is an electronic measurement device to monitor the lung function (determination of the respiratory flows and volume) with high reproducibility wherever and whenever is a need of. The AM1+ / AM1+ BT measures the flow during expiration serving for the calculation of further parameters as FEV1.
The AM1+ / AM1+ BT is used to monitor the respiratory status of human beings in the areas asthma, chronic obstructive pulmonary disorder and in areas like occupational medicine, clinical trials and disease management.
The patient is informed of the results by numeric values for selected parameters (e.g. PEF, FEV1). Furthermore a visual control unit, displayed as a kind of traffic lights, allows an immediate indication of the measurement based on criteria defined by the patient's physician.
The device saves the results of a measurement (always with date and time) automatically in an internal database. The memory capacity is designed to store up to 400 measurements. In addition, a questionnaire functionality can be called up by the use of a software package (AMOS) to record e.g. the "Quality of Life" status. When enabled, the AM1+ / AM1+ BT can be programmed with a couple of questions, where the patient can select then from a couple of different answers. This information is also stored in the internal database and can be transmitted for evaluation to a standard PC using the software package AMOS.
The AM1+ / AM1+ BT is designed to replace ordinary peak flow meter, diary and pencil by a single system. Easy handling, sturdy and handy design allow the Asthma Monitor AM1+ / AM1+ BT being used almost everywhere: at work, at home, in school, for experts opinion, research or clinical trial purposes and in occupational medicine.
The AM1+ operates with serial data transmission whereas the AM1+ BT can be operated with serial and Bluetooth data transmission.

## 5.13 Required Components

Asthma Monitor AM1+ / AM1+ BT
Accessories
User Manual

## 5.14 Summary Table of Comparison

| | Asthma Monitor AM2 (K980876) | Asthma Monitor AM1+ / AM1+ BT |
|---|---|---|
| **Indications for Use** | The Asthma Monitor AM2 from JAEGER is an electronic measurement device to monitor the lung function (determination of the respiratory flows and volume) with high reproducibility wherever and whenever is a need of. The AM2 measures the flow during expiration serving for the calculation of further parameters as FEV1, FVC or FEF25-75. The AM2 is used to monitor the respiratory status of human beings in the areas asthma, chronic obstructive pulmonary disorder and in areas like occupational medicine, clinical trials and disease management.<br>The patient is informed of the results by numeric values for selected parameters (e.g. PEF, FEVI).<br>Furthermore a visual control unit, displayed as a kind of traffic lights, allows an immediate indication of the measurement based on criteria defined by the patient's physician.<br>The device saves the results of a measurement (always with date and time) automatically in an internal database. The memory capacity is designed to store up to 400 measurements. In addition, a questionnaire functionality can be called up by the use of a software package (AMOS) to record e.g. the "Quality of Life" status .When enabled, the AM2 can be programmed with up to 12 questions, where the patient can select then from up to 7 different answers. This information is also stored in the internal database and can be transmitted for evaluation to a standard PC using the software package AMOS.<br>The AM2 is designed to replace ordinary peak flow meter, diary and pencil by a single System. Easy handling, sturdy and handy design allow the Asthma Monitor AM2 being used almost everywhere: at work, at home, in school, for experts opinion, research or clinical trial purposes and in occupational medicine. | The Asthma Monitor AM1+ / AM1+ BT from Cardinal Health is an electronic measurement device to monitor the lung function (determination of the respiratory flows and volume) with high reproducibility wherever and whenever is a need of. The AM1+ / AM1+ BT measures the flow during expiration serving for the calculation of further parameters as FEV1. The AM1+ / AM1+ BT is used to monitor the respiratory status of human beings in the areas asthma, chronic obstructive pulmonary disorder and in areas like occupational medicine, clinical trials and disease management.<br>The patient is informed of the results by numeric values for selected parameters (e.g. PEF, FEV1). Furthermore a visual control unit, displayed as a kind of traffic lights, allows an immediate indication of the measurement based on criteria defined by the patient's physician.<br>The device saves the results of a measurement (always with date and time) automatically in an internal database. The memory capacity is designed to store up to 400 measurements. In addition, a questionnaire functionality can be called up by the use of a software package (AMOS) to record e.g. the "Quality of Life" status. When enabled, the AM1+ / AM1+ BT can be programmed with a couple of questions, where the patient can select then from a couple of different answers. This information is also stored in the internal database and can be transmitted for evaluation to a standard PC using the software package AMOS.<br>The AM1+ / AM1+ BT is designed to replace ordinary peak flow meter, diary and pencil by a single system. Easy handling, sturdy and handy design allow the Asthma Monitor AM1+ / AM1+ BT being used almost everywhere: at work, at home, in school, for experts opinion, research or clinical trial purposes and in occupational medicine.<br>The AM1+ operates with serial data transmission whereas the AM1+ BT can be operated with serial and Bluetooth data transmission. |

| | | |
|---|---|---|
| **Patient population** | The Asthma Monitor can be used for patients from 4 years on and older. | **Identical** |
| **Dimensions** (housing) | Length x Width x Height:<br>112*82*34 mm<br><br>Weight:<br>145 g (batteries included) | **Identical** |
| **Display** | LCD module<br>Size: 46,0 x 18,4 mm<br>100 x 32 dots | **identical** |
| **Key-panel** | Foil Key-panel (4 keys):<br><br>- ESC (on/off)<br>- UP-ARROW<br>- DOWN-ARROW<br>- OK | **identical** |
| **Housing** | Material:<br>Rotec ABS 1001FR V0 | **identical** |
| **Integrated mouthpiece** (Flow sensor) | Material:<br>Rotec ABS 1001FR V0 | Material:<br>Polystyrol 454C |
| **Single Use mouthpiece** (optional) | Material:<br>Bormed RG835 MO | **identical** |
| **Performance** (measurements) | Parameters:<br>PEF / FEV1 / FVC / FEF25 / FEF50<br>FEF75 / FEF25-75 | Parameters:<br>PEF / FEV1 |
| **Interface** | Serial RS 232 | Serial RS 232 & Bluetooth |
| **Energy type** | 3 x 1,5 (Micro AAA) | **identical** |
| **Operating Require-ments** | PC software AMOS | **Identical** |

## 5.15 Summary of Device Testing

The following practices were followed and monitored for development of the Asthma Monitor AM1+ with the Bluetooth data transmission:

The Bluetooth data transmission 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 Asthma Monitor AM1+ / AM1+ BT with the additional Bluetooth data transmission was a Failure Modes and Effects Analysis (FMEA).

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

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 Asthma Monitor AM1+ / AM1+ BT 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 - 6 2009

Cardinal Health Germany 234 GmbH
C/O Mr. Thomas Gutierrez
Director Regulatory Affairs
Cardinal Health 207 Incorporated
Regulatory Affairs, 1100 Bird Center Drive
Palm Springs, California 92262

Re: K090486
Trade/Device Name: Asthma Monitor AM1+ Asthma Monitor AM1+BT
Regulation Number: 868.1840
Regulatory Class: II
Product Code: BZG
Dated: April 2, 2009
Received: April 6, 2009

Dear Mr. Gutierrez:

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 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) 276-0100. 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, D.D.S., M.A.
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): K090486

Device Name: Asthma Monitor AM1+
Asthma Monitor AM1+ BT

Indications for Use:

The Asthma Monitor AM1+ / AM1+ BT from Cardinal Health is an electronic measurement device to monitor the lung function (determination of the respiratory flows and volume) with high reproducibility wherever and whenever is a need of. The AM1+ / AM1+ BT measures the flow during expiration serving for the calculation of further parameters as FEV1.
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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)

Susan Runner

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



510(k) Number: K090486