K092890

510(k) Summary

JAN 13 2010

GENERAL INFORMATION

5.1 Type of Submission

Special 510(k) Submission

Submission date: 09/03/2009

5.2 Submitter

Name: CareFusion Germany 234 GmbH
(formerly: Cardinal Health Germany 234 GmbH)

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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 AM3 / AM3 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"
-- Additional data transfer to computer by blue tooth --

5.9 Legally predicate marketed device

Asthma Monitor AM3
K980676/A2 Code BZG

Asthma Monitor AM1+ / AM1+ BT
K090486 Code BZG

5.10 Predicate Device Company

CareFusion Germany 234 GmbH (formerly: Cardinal Health Germany 234 GmbH)

5.11 Device Description

The Asthma Monitor AM3 is a medical device (peak flow meter with symptom diary) providing following characteristics:

- Handheld device
- Battery operation
- Storing capacity of 400 measurements
- Storing capacity of 200 sets of questionnaires (each 12)
- Measurement Parameters: PEF and FEV1
- Accuracy Flow: ± 5% or ± 20 l/min
- Accuracy Volume: ± 3% or ± 0.05 liter
- Data transmission to computer via USB, Bluetooth and Serial
- Flow sensor (single patient use)
- Mouthpiece (single patient use)

5.12 Intended Use Statement

The Asthma Monitor AM3 / AM3 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 AM3 / AM3 BT measures the flow during expiration serving for the calculation of further parameters as FEV1.
The AM3 / AM3 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 AM3 / AM3 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 AM3 / AM3 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 AM3 / AM3 BT being used almost everywhere: at work, at home, in school, for experts opinion, research or clinical trial purposes and in occupational
medicine.

5.13 Required Components

AM3 / AM3 BT measurement device
Accessories
User Manual

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5.14 Summary Table of Comparison

a) Comparison with Asthma Monitor AM3 with 510(k) K980876/A2

	Asthma Monitor AM3 (K980876/A2)	Asthma Monitor AM3 with Bluetooth
Indications for Use	The Asthma Monitor AM 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 AM measures the flow during expiration serving for the calculation of further parameters as FEV1. The AM 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 AM 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 AM 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 AM being used almost everywhere: at work, at home, in school, for experts opinion, research or clinical trial purposes and in occupational medicine.	**identical**

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Patient population	The Asthma Monitor can be used for patients from 4 years on and older.	**identical**
Dimensions (housing)	Length x Width x Height: 112*82*37 mm Weight: 167 g (batteries included)	**identical**
Display	LCD module Size: 54,0 x 33,5 mm 255 x 160 dots	**identical**
Key-panel	Foil Key-panel (4 keys): - ESC (on/off) - UP-ARROW - DOWN-ARROW - OK	**identical**
Integrated mouthpiece (material)	Polysterol 454C	**identical**
Single Use mouthpiece (material)	Bormed RG835 MO	**identical**
Performance (measurements)	<u>Parameters:</u> PEF FEV1	**identical**
Interface	Serial RS 232 & USB	Serial RS 232 & USB & Blue-tooth
Energy type	3 x 1,5 (Micro AAA)	**identical**
Operating Require-ments	PC software AMOS	**identical**

Discussion to the table above:

The insignificant difference to the AM3 K980876/A2 is:

- ***Bluetooth*** *– is used for data transfer to the computer as an additional* possibility besides the serial and USB interface communication.

b) Comparison with Asthma Monitor AM1+ / AM1+ BT with 510(k) K090486

	Asthma Monitor AM1+ / AM1+ BT K090486	**Asthma Monitor AM3 with Bluetooth**
Bluetooth interface	WML-C46 (Manufacured by Mitsumi Electric Co. LTD)	**Identical**
Bluetooth Power Supply	3.3 Vdc	**Identical**
Bluetooth Transmit Power	2.65 dBm E.I.R.P.	**Identical**
Bluetooth Frequency Range	2.402GHz – 2.480GHz	**Identical**
Bluetooth Modulation Technique	Frequency Hopping Spread Spectrum (FHSS) (GFSK)	**Identical**
Bluetooth Number of Channels	79	**Identical**
Bluetooth Dwell Time	<= 0.4s	**Identical**
Bluetooth Operating Mode	Point-to-Point	**Identical**
Bluetooth Data Rate	741 Kps (Highest Mode)	**Identical**
Bluetooth Antenna Type	Chip Antenna	**Identical**
Bluetooth Antenna Gain	2.0 dBi	**Identical**

Discussion to the table above:

The similarity to the AM1+ / AM1+ BT is found as:

- **Bluetooth** – is used for data transfer. The Bluetooth module for the AM3 device is identical to the Bluetooth module in the AM1+ / AM1+ BT. Both devices work with the Bluetooth module WML-C46 manufactured by Mitsume Electric Co. LTD. As a consequence of this all Bluetooth parameters of the AM3 BT are identical to the predicate device AM1+ BT.

5.15 Summary of Device Testing

The following practices were followed and monitored for development of the Asthma Monitor AM3 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 09 – Design Control).
- The risk analysis method used to assess the impact of Asthma Monitor AM3 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.
- The software was developed according to the IEC 601-1-4 Standard.

5.16 Conclusions

Based on the above, CareFusion Germany 234 GmbH concludes that the Asthma Monitor AM3 with the "Bluetooth" data transmission module 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
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Ms. Elmar Niedermeyer
Regulatory Affairs Specialist
CareFusion Germany 234 GmbH
Leibnizstrasse 7
Hoechberg
GERMANY 97204

JAN 13 2010

Re: K092890
Trade/Device Name: AM3 AM3BT
Regulation Number: 21CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: II
Product Code: BZG
Dated: December 3, 2009
Received: December 14, 2009

Dear Ms. Nidermeyer:

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,

for

Anthony D. Watson, BS, MS, MBA
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): K

Device Name: AM3
AM3 BT

Indications for Use:

The Asthma Monitor AM3 / AM3 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 AM3 / AM3 BT measures the flow during expiration serving for the calculation of further parameters as FEV1.
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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 600 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 AM3 / AM3 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.
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medicine.

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)

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

510(k) Number: K092890