SEP 1 3 2005

510(k) Summary K050760

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 521-2000 ext. 3362
Contact Person: Scott Thiel
Date Prepared: March 23, 2005

2) Device name

Proprietary name: ACCU-CHEK® Pocket Compass Diabetes Management Software
Common name: diabetes management software
Classification name: calculator/data processing module for clinical use
Classification Regulations: 880.5725, 862.1345, 862.2100
Product Codes: LZG, LFR, JQP

3) Predicate device

We claim substantial equivalence to the current legally cleared Animas ezManager Plus Software.

4) Device Description

An accessory software that enables the person with diabetes and their health care professionals in review, analysis and evaluation of historical blood glucose test results and insulin infusion pump data to support effective diabetes management, including calculating an insulin or carbohydrate dose based on user entered data. The device is not intended to provide any diagnosis based upon patient results.

5) Intended use

The ACCU-CHEK Pocket Compass Diabetes Management Software is a single user system indicated for use as an accessory to compatible Disetronic insulin pumps and a number of commercially available Accu-Chek blood glucose meters to download data from these devices to a personal digital assistant (PDA) where it may be saved, displayed, reviewed, analyzed, and evaluated to support effective diabetes management. The Accu-Chek Pocket Compass Software is also indicated for the management of diabetes by calculating an insulin or carbohydrate dose based on user entered data. The device is indicated for over-the-counter sale.

Continued on next page

510(k) Summary, Continued K052700

Comparison to Predicate Device

Similarities The Roche Diagnostics ACCU-CHEK Pocket Compass Diabetes Management Software is substantially equivalent to the current legally cleared version Animas ezManager Plus Software. The following is a list of some of the claims and features found to be similar to the predicate device.

Feature/Claim	Detail
Meter data upload	Yes.
Support	Yes; through call center support, labeling and health care professionals.
Data storage	On computer media.
Reports and graphs	Similar graphs and reports can be generated for viewing on a display screen, and hard copy printout.
Manual Data Entry	Similar methods of manually entering data into the software.
Delete Data	Similar methods of deleting data.
Track non-blood glucose data	Tracks similar data sets. (i.e. Carbohydrates, insulin, time blocks, event codes).
Intended Use	Both products are indicated for use as an accessory to insulin infusion pumps and blood glucose monitors. Both products provide for electronic download of data from these devices. Both products provide and insulin or carbohydrate dose based upon user entered data.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 13 2005

Mr. Scott Thiel
Regulatory Affairs Program Principal
Roche Diagnostics
9115 Hague Road
Indianapolis, Indiana 46250

Re: K050760
Trade/Device Name: Accu-Chek Pocket Compass Diabetes Management Software
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion pump
Regulatory Class: II
Product Code: LZG
Dated: August 23, 2005
Received: August 25, 2005

Dear Mr. Thiel:

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) 276-0115. 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): K050760

Device Name: ACCU-CHEK® Pocket Compass Diabetes Management Software

Indications For Use:

The ACCU-CHEK Pocket Compass Diabetes Management Software is a single user system indicated for use as an accessory to compatible Disetronic insulin pumps and a number of commercially available Accu-Chek blood glucose meters to download data from these devices to a personal digital assistant (PDA) where it may be saved, displayed, reviewed, analyzed, and evaluated to support effective diabetes management. The Accu-Chek Pocket Compass Software is also indicated for the management of diabetes by calculating an insulin or carbohydrate dose based on user entered data. The device is indicated for over-the-counter sale.

Prescription Use _____ AND/OR Over-The-Counter Use __XX____
(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)

Page 1 of _____

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

510(k) Number: K050760