K062395

MAY - 9 2007

510(k) Summary: ACCU-CHEK® Smart Pix Device

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.
Submitter name, address, contact	Roche Diagnostics 9115 Hague Rd. Indianapolis, IN 46250 Contact Person: Scott Thiel Data Prepared: March 27, 2007
Device Name	We claim substantial equivalence to the current legally marketed ACCU-CHEK® Acculink Modem.
Device Description	Accessory to ACCU-CHEK® brand meters and/or Disetronic/ACCU-CHEK insulin infusion pump that enables the persons with diabetes or healthcare professionals to send stored data to a compatible computer.
Indications for Use Statement	The ACCU-CHEK® Smart Pix enables persons with diabetes or healthcare professionals to send stored data from their compatible ACCU-CHEK blood glucose monitor and/or Disetronic/ACCU-CHEK Insulin infusion pump to a compatible computer as a set of reports or data stream. The ACCU-CHEK Smart Pix is intended to help monitor and clinically manage individuals with diabetes.

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510(k) Summary: ACCU-CHEK® Smart Pix Device, Continued

Similarities

The proposed modification is relatively modest in scope. The following is a list of some of the claims and features unaffected by the proposed modifications.

Feature / Claim	Detail
Connect to blood glucose monitors	Both devices connect to and download information stored on ACCU-CHEK brand blood glucose monitors.
Warnings and precautions	For in vitro diagnostic use only.
State Messaging	Both devices provide feedback to the consumer through a combination of LED flashes.
Reports	Both devices create reports and graphs using basic statistical calculations of the historic data stored in the devices they can connect to.

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Differences

The following is a listing of the key differences between the ACCU-CHEK Smart Pix and the predicate device.

Feature / Claim	ACCU-CHEK Smart Pix	Predicate
Power supply	USB port	AC adapter
Weight	90 g	205 g
Size	104 x 74 x 38 mm	137 x 113 x 41 mm
Intended use	The ACCU-CHEK® Smart Pix enables persons with diabetes or healthcare professionals to send stored data from their compatible ACCU-CHEK blood glucose monitor and/or Disetronic/ACCU-CHEK Insulin infusion pump to a compatible computer as a set of reports or data stream. The ACCU-CHEK Smart Pix is intended to help monitor and clinically manage individuals with diabetes.	The ACCU-CHEK® Acculink modem is designed to enable the self-tester to send data from a supported Accu-Chek brand meter to either a facsimile (fax) machine or Roche supported software utilized by a physician, pharmacist, or other member of the self-tester's health care team. The data transmission takes place over standard telephone service (POTS) lines or telephone line emulator.
Ambient conditions	Service temperature: 5 – 40 C Storage temperature: -25 – 70 C Humidity: 9.6 – 98% Rh	Operating temperature: 0 – 50 C Storage temperature: -25 – 65 C Humidity: 0 – 95% Rh

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY - 9 2007

Roche Diagnostics Corp.
c/o Mr. Scott Thiel
Global Regulatory Affairs
Diabetes Care
9115 Hague Road
Indianapolis, IN 46256

Re: k062395
Trade/Device Name: ACCU-CHEK® Smart Pix
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, LZG, JQP
Dated: March 28, 2007
Received: March 29, 2007

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062395

Device Name: ACCU-CHEK® Smart Pix

Indications For Use:

The ACCU-CHEK® Smart Pix enables persons with diabetes or healthcare professionals to send stored data from their compatible ACCU-CHEK blood glucose monitor and/or Disetronic/ACCU-CHEK Insulin infusion pump to a compatible computer as a set of reports or data stream.

The ACCU-CHEK Smart Pix is intended to help monitor and clinically manage individuals with diabetes.

Prescription Use ___XX_ (Part 21 CFR 801 Subpart D) (AND/OR) Over-The-Counter Use _XX___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Jean M. Cooper, M.S., D.V.M

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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