Roche Diagnostics Corporation
Scott Thiel
Regulatory Affairs Program Principal
Patient Care Division
9115 Hague Road
Indianapolis, Indiana 46250

May 17, 2024

Re: K043529
Trade/Device Name: ACCU-CHEK® Advisor Insulin Guidance Software
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive pulmonary-function value calculator
Regulatory Class: Class II
Product Code: NDC

Dear Scott Thiel:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated April 8, 2005. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product code NDC.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Juliane Lessard, OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices, 240-402-6126, Juliane.Lessard@fda.hhs.gov.

Sincerely,

Juliane C. Lessard -S

Juliane C. Lessard, Ph.D.
Director
DHT3C: Division of Drug Delivery,
General Hospital and Human Factors Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 8 2005

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

Re: K043529
Trade/Device Name: ACCU-CHEK® Advisor Insulin Guidance Software
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: None
Product Code: LNX
Dated: March 30, 2005
Received: March 31, 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.

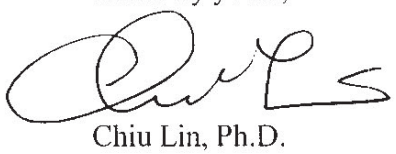
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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): K043529

Device Name: ACCU-CHEK® Advisor Insulin Guidance Software

Indications For Use:

The software is intended for use in home and clinical settings to aid people with diabetes and their health care professionals in review, analysis and evaluation of historical blood glucose test results to support effective diabetes management, including providing direction within the scope of a pre-planned treatment program for adjustments to prescribed insulin, similar to the directions physicians provide to patients as a part of routine clinical practice. The device is not intended to provide any diagnosis on patient results.

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

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

(510(k) Number) K043529

K043523

APR 8 2005

510(k) Summary

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: December 17, 2004

2) Device name

Proprietary name: ACCU-CHEK® Advisor Insulin Guidance Software
Common name: diabetes management software
Classification name: computers and software, medical
Product Code: LNX

3) Predicate device

We claim substantial equivalence to the current legally cleared Diacare Monitoring System 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 to support effective diabetes management, including providing direction within the scope of a pre-planned treatment program for adjustments to prescribed insulin, similar to the directions physicians provide to patients as a part of routine clinical practice.

5) Intended use

The software is intended for use in home and clinical settings to aid people with diabetes and their health care professionals in review, analysis and evaluation of historical blood glucose test results to support effective diabetes management, including providing direction within the scope of a pre-planned treatment program for adjustments to prescribed insulin, similar to the directions physicians provide to patients as a part of routine clinical practice. The device is not intended to provide any diagnosis on patient results.

Continued on next page

510(k) Summary, Continued

Comparison to Predicate Device

Similarities The Roche Diagnostics ACCU-CHEK Advisor Insulin Guidance is substantially equivalent to the current legally cleared version Diacare Monitoring System 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, timeblocks, event codes).