K012324

Accu-Chek Active Test System

DEC 0 5 2001

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.

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1) Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 845-2000

Contact Person: Mike Flis

Date Prepared: July 20, 2001

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2) Device name

Proprietary name: Accu-Chek Active Test System
Common name: Blood glucose test system
Classification name: glucose dehydrogenase, glucose

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3) Predicate device

The Roche Diagnostics Accu-Chek Active Test System is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the recently cleared version of the same product. In addition, the AST claim described in this 510(k) premarket notification is substantially equivalent to claims cleared for the following medical devices.

- Lifescan/Inverness One Touch Ultra Test System (K002134—Special)
- Abbott/Medisense Sof-Tact Test System (K001993—Traditional)
- Therasense Freestyle Test System (K992684—Traditional)
- Lifescan/Inverness FastTake Test System (K001427—Special)

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4) Device Description

The Accu-Chek Active Test System includes a handheld meter, lancet device, lancets, and instructions for use. Test strips and liquid controls may be acquired separately.

Continued on next page

510(k) Summary, Continued

5) Intended use	The Accu-Chek Active system is designed to quantitatively measure the concentration of glucose in capillary whole blood. The device is indicated for professional use and over-the-counter sale.
6) Comparison to predicate device	The Accu-Chek Active Test System is substantially equivalent to other products in commercial distribution intended for similar use.

Comparison to Predicate Devices

	Accu-Chek Active with AST	Accu-Chek Active	Amira AtLast	Therasense Freestyle	Medisense Sof-Tact	Lifescan One Touch Ultra	Lifescan FastTake
510(k) (T) = Trad. (S) = Special		K011738 (S)	K982076 (T)	K992684 (T) & K000582 (S)	K001993 (T)	K002134 (S)	K001427 (S)
510(k) Sponsor	Roche	Roche	Amira	Therasense	Abbott	Inverness	Inverness
Intended Use	Blood glucose monitoring	Blood glucose monitoring	Blood glucose monitoring	Blood glucose monitoring	Blood glucose monitoring	Blood glucose monitoring	Blood glucose monitoring
OTC sale	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Minimum sample volume required (μL)	1	1	2	0.3	3	1	1.5
Fingertip	Yes	Yes	No	Yes	Yes	Yes	Yes
AST	Yes	No	Yes	Yes	Yes	Yes	Yes
AST limited to forearm only	Yes	NA	No	No	No	Yes	Yes
Underdosing detection	Yes	Yes	Yes	Yes	No	No	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Mike Flis
Regulatory Affairs Principal
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250-0457

DEC 0 5 2001

Re: k012324
Trade/Device Name: Accu-Chek Active Test System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: November 8, 2001
Received: November 13, 2001

Dear Mr. Flis:

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 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):
Device Name: Accu-Chek Active Test System

Indications for Use:

The Accu-Chek Active system is designed to quantitatively measure the concentration of glucose in capillary whole blood. The device is indicated for professional use and over-the-counter sale.

(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 Clinical Laboratory Devices
510(k) Number K012524

Prescription Use _____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)