

AUG 28 1998

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/Boehringer Mannheim Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(800) 428-5074

Contact Person: Mike Flis

Date Prepared: June 12, 1998

2) Device name Proprietary name: Accu-Chek Voicemate
Common name: self-monitoring blood glucose test system
Classification name: glucose test system

3) Predicate device Boehringer Mannheim Accu-Chek II Freedom

4) Device Description The Accu-Chek Voicemate is a portable blood glucose test system. The Accu-Chek Voicemate incorporates proven technologies, such as the Accu-Chek® Advantage® Monitor, Accu-Chek™ Comfort Curve™ Test Strips, and Accu-Chek™ Softclix® Lancet Device.

The Accu-Chek Voicemate differs from the currently available devices in that it introduces a new function that will be especially helpful to the visually impaired insulin-using diabetics. We have worked in partnership with Eli Lilly & Company to develop a bar code reader that will reliably read bar codes printed on the insulin vials distributed by Eli Lilly. The bar code reader will help the visually impaired customers distinguish their insulin vials.

Continued on next page

510(k) Summary, Continued

5) **Intended use** Designed for testing glucose in whole blood by visually impaired persons with diabetes.

6) Comparison to predicate device

Function	Accu-Chek Voicemate (new device)	Accu-Chek II Freedom (predicate device)
Intended Use/Indications for Use	Designed for testing glucose in whole blood by visually impaired persons with diabetes	Accu-Chek II Freedom Audio SBGM System for the Visually Impaired is a rechargeable, battery operated system for visually impaired people with diabetes that will accurately measure blood glucose levels
Incorporate which Self-Monitoring Blood Glucose System	Accu-Chek Advantage Meter Accu-Chek Comfort Curve Test Strips	Accu-Chek II Meter Chemstrip bG Test Strips
Blood Collection Device	None required. The test strips permit the user to dose by applying a drop of blood to the edge of the test strips. A "curve" is cut into the test strip so that the exact location of the dose is discernable through touch. The patient may also touch the test strip while dosing the test strip without damaging the strips' reagent or compromising the test result.	Accu-Drop™. The Chemstrip bG test strips required the user to dose the test strips using the Accu-Drop device (which guided the blood sample to the test strips' reagent pad).
Preanalytic test strip preparation	None required. Accu-Chek Comfort Curve Test Strips do not require the user to time any of the procedural steps, blot away blood, or intervene in any manner once the strip has been dosed. The test strip is inserted into the meter before the blood drop is applied.	The Chemstrip bG Test Strip required the users to time the first step of the procedure, wipe away excess blood from the strip and then insert the test strip into the meter.
Insulin vial label reader	Device is capable of reading bar codes printed on specific insulin vial types. The device's embedded software defines which insulin vial labels may be read.	Function not available



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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mike Flis
. Regulatory Affairs Specialist
Boehringer Mannheim
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250-0457

Re: K982079
Accu-Chek™ Voicemate™ System
Regulatory Class: II
Product Code: LFR
Dated: June 12, 1998
Received: June 15, 1998

Dear Mr. Flis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

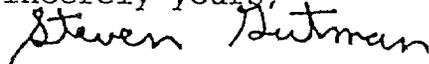
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



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

510(k) Number (if known):
Device Name: Accu-Chek™ Voicemate™ System
Indications for Use:

Designed for testing glucose in whole blood by visually impaired persons with diabetes.

The product will be marketed over-the-counter.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

CA H... for Alfred...
(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K98 2079

~~Prescription Use~~
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)