

OCT - 9 1997

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 Boehringer Mannheim Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 845-2000

Contact Person: Mike Flis

Date Prepared: August 01, 1997

2) Device name Proprietary name: Glucotrend™ Basic System

Common name: self-monitoring blood glucose test system

Classification name: Blood glucose test

3) Predicate device We claim substantial equivalence to the Boehringer Mannheim Accu-Chek Advantage System with the Advantage H Test Strip.

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510(k) Summary, Continued

4) Device Description Instrument Operating Principle -- photometric
Reagent Test Principle -- glucose deoxy reductase

5) Intended use The Glucotrend Basic System is designed for testing glucose by persons with diabetes or by health care professionals in the home or in health care facilities.

6) Comparison to predicate device The Boehringer Mannheim Glucotrend Basic System is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Boehringer Mannheim Accu-Chek Advantage System with the Advantage H Test Strip.

Similarities to Predicate Device

- Intended use (blood glucose monitoring)
- Closed system (instrument and reagents are provided by BMC and are intended to only be used in conjunction with each other)
- Glucose dehydrogenase test principle
- Verified reportable range (10 to 600 mg/dL)
- Test strip packaging (desiccated vials with multiple strips)
- Test strip storage conditions
- Recommended quality control testing procedure
- Specimen collection and preparation instructions
- Monitor requires no scheduled maintenance other than cleaning
- Instructions regarding response to unusual results
- Warnings and precautions
- Results referenced to whole blood laboratory testing

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510(k) Summary, Continued

Differences

Feature	Accu-Chek Advantage System with the Advantage H Test Strip (predicate)	Glucotrend Basic (new device)
Instrument operating principle	amperometric	photometric
Blood sample types	capillary, venous, arterial, and neonate	capillary and venous
Minimum sample volume	9 μ L	3 μ L
Operating temperature range	14°C to 40°C	10°C to 40°C
Hematocrit range	20-65% at <200 mg/dL 25-55% at >200 mg/dL	30-57%
Maximum altitude verified	10,150 feet	9500 feet
Visual result back-up	None	Blank + 5 color blocks on strip canister
Interferences	Low concentration: • Xylose High concentration: • Uric Acid • Galactose • Lipemic sample > 5000 mg/dL	Low concentration: • Xylose High concentration: • Uric Acid • Galactose

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510(k) Summary, Continued

Performance Characteristics Accuracy

Parameter	Accu-Chek Advantage System with the Advantage H Test Strip (predicate)	Glucotrend Basic (new device)
Trained health care professional versus reference (Capillary blood)	N = 166 $y = 0.99x + 5.0$ $r = 0.973$ range = 43 to 478 mg/dL	N = 202 $y = 1.02x + 2.6$ $r = 0.989$ range = 51 to 490 mg/dL
Trained health care professional versus reference (Venous blood)	N = 166 $y = 1.05X - 0.6$ $r = 0.990$ range = 40 to 457 mg/dL	N = 104 $y = 1.029 x + 2.7$ $r = 0.995$ range = 35 to 483 mg/dL
Arterial blood study	N = 206 $y = 1.06x - 3.5$ $r = 0.973$	not applicable
Neonate blood study	N = 303 $y = 0.98x + 2.81$ $r = 0.94$ range = 20 to 305 mg/dL hematocrit range = 26 to 69%	not applicable
Consumers versus reference	Not performed--claim data from glucose oxidase test strip supports OTC use	N = 134 $y = 1.082x - 2.9$ $r = 0.976$ range = 58 to 357 mg/dL

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510(k) Summary, Continued

Performance
Characteristics,
Contd.

Precision

Parameter	Accu-Chek Advantage System with the Advantage H Test Strip (predicate)	Glucotrend Basic (new device)
	N = 96/Level (Control) N = 60/Level (Blood)	N = 20/Level
Control Level 1 •Mean (mg/dL) •Standard Deviation (SD)	42.0 4.2	84.0 2.0
Control Level 2 •Mean (mg/dL) •Standard Deviation (SD)	104.0 3.0	196.4 2.5
Venous Blood Level 1 •Mean (mg/dL) •Standard Deviation (SD)	53.0 3.9	28.7 1.2
Venous Blood Level 2 •Mean (mg/dL) •Standard Deviation (SD)	not applicable	87.3 2.6
Venous Blood Level 3 •Mean (mg/dL) •Standard Deviation (SD)	not applicable	129.4 3.0
Venous Blood Level 4 •Mean (mg/dL) •Standard Deviation (SD)	233.0 2.9	229.2 2.8
Venous Blood Level 5 •Mean (mg/dL) •Standard Deviation (SD)	490.0 3.6	335.0 3.4

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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT - 9 1997

Mr. Mike Flis
Boehringer Mannheim Corporation
9115 Hague Road
Indianapolis, Indiana 46250

Re: K972876
Trade Name: Glucotrend™ Basic System
Regulatory Class: II
Product Code: LFR
Dated: July 31, 1997
Received: August 4, 1997

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 requirement, 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.

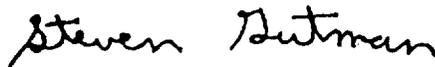
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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 at (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

Indications for Use Statement

510(k) Number (if known):

Device Name: Glucotrend Basic System

Indications for Use:

The Glucotrend Basic System is designed for testing glucose by persons with diabetes or by health care professionals in the home or in health care facilities.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)


(Division Sign-Off)
Division of Clinical Laboratories & Devices

510(k) Number KC972876

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