

MAY 7 1998

510(k) Summary**Submitter's Name/Address**

Abbott Laboratories
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Contact Person

Mark Littlefield
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Regulatory Affairs
(972) 518-7861
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Date of Preparation of this Summary:

March 31, 1998

Device Trade or Proprietary Name:

Glu

Device Common/Usual Name or Classification Name: Glucose**Classification Number/Class:**

75CFR/Class II

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____.

Test Description:

Glucose is an *in vitro* diagnostic assay for the quantitative determination of glucose in human serum, plasma, urine, or cerebrospinal fluid (CSF). The Glucose assay is a clinical chemistry assay in which glucose is phosphorylated by hexokinase (HK) in the presence of adenosine triphosphate (ATP) and magnesium ions to produce glucose-6-phosphate (G-6-P) and adenosine diphosphate (ADP).

Glucose-6-phosphate dehydrogenase (G-6-PD) specifically oxidizes G-6-P to 6-phosphogluconate with the concurrent reduction of nicotinamide adenine dinucleotide (NAD) to nicotinamide adenine dinucleotide reduced (NADH). One micromole of NADH is produced for each micromole of glucose consumed. The NADH produced absorbs light at 340 nm and can be detected spectrophotometrically as an increased absorbance.

Substantial Equivalence:

The Glucose assay is substantially equivalent to the following devices:

- Roche® Cobas Mira® Plus Automated Chemistry System Glucose assay (K953847) for the serum application
- Boehringer Mannheim® Glucose/HK assay on the Hitachi® 717 Analyzer (K812303) for the urine and CSF applications

These assays yield similar Performance Characteristics.

Similarities to Roche:

- Both assays are *in vitro* clinical chemistry methods.
- Both assays can be used for the quantitative determination of glucose.
- Both assays yield similar clinical results.

Differences to Roche:

- There is a minor difference between the assay range.

Similarities to Boehringer Mannheim:

- Both assays are *in vitro* clinical chemistry methods.
- Both assays can be used for the quantitative determination of glucose.
- Both assays yield similar clinical results.

Differences to Boehringer Mannheim:

- There is a minor difference between the assay range.

Intended Use:

The Glucose assay is used for the quantitation of glucose in human serum, plasma, urine, or cerebrospinal fluid (CSF) on the ALCYON 300/300i Analyzer.



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 7 1998

Mark Littlefield
. Section Manager, Regulatory Affairs
Abbott Laboratories
1920 Hurd Drive
Irving, Texas 75038

Re: K981185
Glucose
Regulatory Class: II
Product Code: CFR
Dated: March 31, 1998
Received: April 2, 1998

Dear Mr. Littlefield:

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.

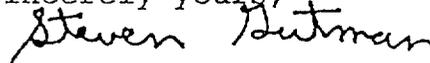
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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

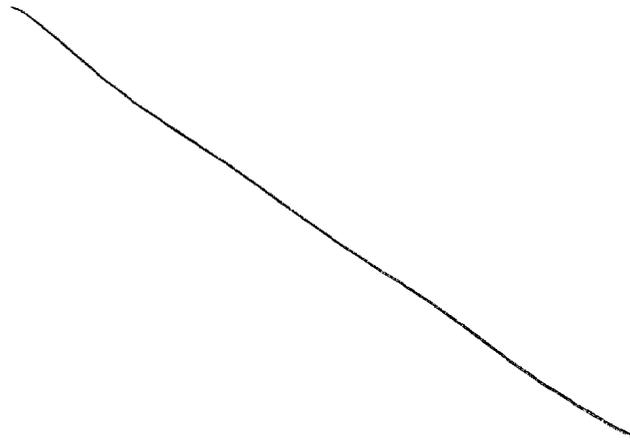
Enclosure

510(k) Number (if known): _____

Device Name: Glucose

Indications For Use:

The Glucose assay is used for the quantitation of glucose in human serum, plasma, urine, or cerebrospinal fluid (CSF) on the ALCYON 300/300i Analyzer. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.





(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number k 781185

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

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)