K981706

JUL 9 1998

510(k) Summary

Submitter's Name/Address
Abbott Laboratories
1920 Hurd Drive
Irving, Texas 75038

Contact Person
Mark Littlefield
Section Manager MS 1-8
ADD Regulatory Affairs
(972) 518-6062
Fax (972) 753-3367

Date of Preparation of this Summary: May 13, 1998

Device Trade or Proprietary Name: Amm Cal, Bil Cal, CO_2 Cal, HDL Cal, Iron/Mg Cal, LDL Cal, MC Cal, UPro Cal, and ISE Calibrator Levels 1 and 2.

Device Common/Usual Name or Classification Name: Abbott Clinical Chemistry Calibrators

Classification Number/Class: 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: _____.

Intended Use:

The Ammonia Calibrator is intended for *in vitro* diagnostic use in clinical chemistry assays for Ammonia.

The Bilirubin Calibrator is intended for *in vitro* diagnostic use in clinical chemistry assays for Bilirubin.

The Carbon Dioxide Calibrator is intended for *in vitro* diagnostic use in clinical chemistry assays for Carbon Dioxide.

The HDL Calibrator is intended for *in vitro* diagnostic use in clinical chemistry assays for HDL.

The Iron/Magnesium Calibrator is intended for *in vitro* diagnostic use in clinical chemistry assays for Iron and Magnesium.

The LDL Calibrator is intended for *in vitro* diagnostic use in clinical chemistry assays for LDL.

The MC Calibrator is intended for *in vitro* diagnostic use in clinical chemistry assays for Albumin, Calcium, Cholesterol, Creatinine, Glucose, Phosphorus, Total Protein, Triglyceride, Urea Nitrogen, and Uric Acid.

The UPro Calibrator is intended for *in vitro* diagnostic use in clinical chemistry assays for protein in urine and CSF.

The ISE Calibrator Levels 1 and 2 are intended for *in vitro* diagnostic use in clinical chemistry assays for Sodium, Potassium, and Chloride.

Conclusion: Abbott Clinical Chemistry Calibrators were used for the calibration of each clinical chemistry reagent on the ALCYON 300/300i. The calibration curve generated was used for the quantitation of each analyte for the purpose of collecting performance data in support of the reagent 510(k) as outlined on the next page.

Calibrator Name	Reagent Name	Reagent 510(k) Number
Ammonia Calibrator	Ammonia	K981467
Liquid Bilirubin Calibrator	Total Bilirubin	K981336
	Direct Bilirubin	K981222
Carbon Dioxide Calibrator	Carbon Dioxide	K981231
HDL Calibrator	Direct HDL	K981224
Iron/Magnesium Calibrator	Iron	K981241
	Magnesium	K981192
LDL Calibrator	Direct LDL	K981303
ISE Calibrator Levels I and Level 2	Sodium Potassium Chloride	K974779
Multiconstituent Calibrator	Albumin BCG	K981468
	Albumin BCP	K981457
	Calcium	K981232
	Cholesterol	K981476
	Creatinine	K981240
	Glucose	K981185
	Phosphorus	K981118
	Total Protein	Exempt Class II
	Triglyceride	K981223 (Exempt Class I)
	Urea Nitrogen	K981123
	Uric Acid	K981189
Urine/CSF Protein Calibrator	Urine/CSF Protein	K981295

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 9 1998

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

Re: K981706
Amm Cal, Bil Cal, CO_2 Cal, HDL Cal, Iron/Mg Cal, LDL Cal, MC Cal, Upro Cal, and ISE Calibrator Levels 1 and 2
Regulatory Class: II
Product Code: JIX
Dated: May 13, 1998
Received: May 14, 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.

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 "dsmo@fdadr.cdrh.fda.gov".

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

510(k) Number (if known): _____

Device Name: Abbott Clinical Chemistry Calibrators

Indications For Use:

An Abbott Clinical Chemistry Calibrator is a device intended for medical purposes for use in a test system to establish points of reference that are used in the determination of values in the measurement of substances in human specimens.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K981706

(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)