200 South Kraemer Boulevard, Box 8000, Brea, CA 92822-8000 • (714) 993-5321 K973932

BECKMAN

DEC 15 1997

Summary of Safety & Effectiveness
Beckman Calibrator 2 (CAL2)

1.0 Submitted By:

Annette Hellie
Sr. Regulatory Specialist, Product Submissions
Beckman Instruments, Inc.
200 S. Kraemer Blvd., W-337
Brea, California 92822-8000
Telephone: (714) 993-8767
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2.0 Date Submitted:

October 14, 1997

3.0 Device Name(s):

3.1 Proprietary Names

Beckman Calibrator 2 (CAL2)

3.2 Classification Name

Calibrator (21 CFR § 862.1150)

4.0 Predicate Device(s):

Device	Predicate	Manufacturer	Docket Number
Beckman Calibrator 2	Beckman Calibrator 2	Beckman Instruments, Inc.	K771603 (AAT) K780913 (PFB) K791339 (CER) K791340 (AMG) K901977 (AT3) K940353 (B2M)

5.0 Description:

Beckman Calibrator 2 is derived from fresh frozen human plasma that has been defibrinated and processed. Assay of CAL 2 provides a response value that is utilized for the adjustment of pre-programmed calibration curves from which AAT, CER, PFB, B2M, AMG, and AT3 concentration values are determined for test specimens.

6.0 Intended Use:

CAL 2 (Calibrator 2), when used in conjunction with Beckman alpha$_1$-antitrypsin (AAT), ceruloplasmin (CER), properdin factor B (PFB), beta-2-microglobulin (B2M), alpha$_2$-macroglobulin (AMG) and antithrombin III (AT3) reagents, is intended for used on Array®, Array® 360, and IMMAGE™ Systems for the calibration of these reagents.

7.0 Comparison to Predicate(s):

The Beckman Calibrator 2 is a lyophilized human serum matrix identical to the current product. The only difference is the additional instrument platform on which it will be used. The existing Beckman CAL 2 is used with Beckman's Array® and Array® 360 Immunochemistry Systems. These systems are fully automated, specific protein analyzers, that measure by nephelometry. The new instrument platform, the IMMAGE™ Immunochemistry System, is also a fully automated, specific protein analyzer that measures by nephelometry.

8.0 Summary of Performance Data:

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to chemistry test systems already in commercial distribution. The value assignment process for each analyte is correlated to a known standard via the anchor method. The Beckman Calibrator 2 value assignment and verification processes yield acceptable calibrator assigned values for calibration on the Array® and IMMAGE™ Systems.

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 15 1997

Annette Hellie
Senior Regulatory Specialist
Beckman Instruments, Inc.
200 S. Kraemer Boulevard, W-337
P.O. Box 8000
Brea, California 92822-8000

Re: K973932
Beckman Calibrator 2
Regulatory Class: II
Product Code: JIX, JZG, CZP, DCF, DDB, DEB, JBQ
Dated: October 14, 1997
Received: October 15, 1997

Dear Ms. Hellie:

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 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: **Beckman Calibrator 2 (CAL2)**

Indications for Use:

CAL 2 (Calibrator 2), when used in conjunction with Beckman alpha$_1$-antitrypsin (AAT), ceruloplasmin (CER), properdin factor B (PFB), beta-2-microglobulin (B2M), alpha$_2$-macroglobulin (AMG) and antithrombin III (AT3) reagents, is intended for used on Array®, Array® 360, and IMMAGE™ Systems for the calibration of these reagents.

21 CFR 862.1150 Calibrator

(a) Identification. A calibrator if 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.

(b) Classification. Class II

(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 Laboratory Devices
510(k) Number K973932