MAR 28 2000

K994278

SUMMARY OF SAFETY AND EFFECTIVENESS

1.0 **SUBMITTED BY:**

Jill Kull, RAC, Staff Regulatory Specialist
Beckman Coulter Inc., 7330 Carroll Rd. / P.O. Box 269006,
San Diego, CA 92196-9006
Telephone: (858) 621-4584 FAX: (858) 621-4752
e-mail: jfkull@beckman.com

2.0 DATE SUBMITTED:

March 14, 2000

3.0 DEVICE NAME(S)

3.1 Proprietary Names
Access® Ostase® Assay on the Access Immunoassay Analyzer

3.2 Classification Names
Bone alkaline phosphatase (BAP) test system.

4.0 PREDICATE DEVICE

Beckman Coulter Product	Predicate	Predicate Company	Docket Number
Access® Ostase® Assay	Tandem®-R Ostase® Assay	Beckman Coulter, Inc.	K961573

5.0 DESCRIPTION OF THE DEVICE

The Access Ostase Assay is a paramagnetic particle, chemiluminescent immunoassay for use with the Access Immunoassay System for the quantitative measurement of bone alkaline phosphatase (BAP), an indicator of osteoblastic activity, in human serum and plasma.

6.0 INTENDED USE OF THE DEVICE

This device is intended to be used as an aid in the management of postmenopausal osteoporosis and Paget's disease.

7.0 COMPARISON TO THE PREDICATE

Technological Characteristic	Access Ostase	Tandem-R Ostase (Predicate)
Analyte Measured	Human bone alkaline phosphatase	Same
Intended Use	Aid in the management of postmenopausal osteoporosis and Paget's disease	Same
Solid Phase Antibody	Monoclonal antibody to BAP	Same
Specimen Matrix	Human serum and plasma	Human serum
Assay Signal	Enzymetric/ Luminometer	Radiometric/ Gamma Counter
Assay Solid Phase	Magnetic particles	Bead
System Method	Automated	Manual

8.0 SUMMARY OF PERFORMANCE DATA

8.1 Method Comparison Study Results

Access Ostase vs. Tandem-R Ostase

Slope	Intercept	r	N
0.9756	-0.5987	0.9895	172

Mean % Differences Between Access Ostase and Tandem-R Ostase

Populations	N (# pairs)	Mean %Difference*	Standard Deviation
Osteoporosis	88	-5.96%	12.37%
Paget's	84	-7.01%	14.25%

* Mean % Difference = [(Access -Tandem)/(Access+ Tandem/2)] X 100

8.2 Imprecision Summary

The between-run %CV observed across the concentrations tested ranged from 3.3% to 5.9%. The within-run %CV observed across the concentrations tested ranged from 1.5% to 2.6%. The total %CV observed across the concentrations tested ranged from 3.6% to 6.4%.

8.3 Recovery and Specimen Dilution

The results of spike and recovery across 15 samples ranged from 89.9% to 95.3% with an average recovery of 92.4%.

The results for ten (10) samples in the dilution study ranged from 78.1% to 106.1% with an average recovery of 92.2%. Regression analysis of these data yielded slopes ranging from 0.9280 to 1.0075 with an overall average slope of 0.9682. Correlation coefficients (r) ranged from 0.9999 to 0.9983 with an overall average correlation coefficient of 0.9994.

8.4 Interfering Substances

The following substances and concentrations were evaluated for interference in the Access Ostase Assay. There is no significant interference from any of the substances tested at these concentrations.

Substance	Concentration Tested	Substance	Concentration Tested
Acetaminophen	35 mg/dL	Ibuprofen	40 mg/dL
alendronate	8 mg/dL	Pamidronate	18 mg/dL
Aspirin	50 mg/dL	progesterone	25 mg/dL
bilirubin – unconjugated conjugated	 40 mg/dL 20 mg/dL	protein	3.8 and 15.6 g/dL
calcitonin-salmon	112 IU/dL	raloxifene	12 mg/dL
Calcium	40 mg/dL	risedronate	6 mg/dL
estrogen	10 mg/dL	triglycerides	2000 mg/dL
etidronate	105 mg/dL	vitamin D	80,500 IU/dL
hemoglobin	500 mg/dL		

In summary, there is no significant interference from any of the substances tested at the concentrations listed above.

8.5 Reactivity with Intestinal, Placental and Liver Alkaline Phosphatase Isoenzymes

In these studies, 100 U/L of intestinal alkaline phosphatase yielded a result of 1.8 μg/L in the Access Ostase Assay. 100 U/L of placental alkaline phosphatase activity yielded a result of 0.3 μg/L in the Access Ostase Assay.

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.

Question 4. Please add a statement at the beginning of the clinical trial section indicating that all the clinical trials were performed with the Tandem-R.

Answer: The following statement was added to page 5 (page 95 of the original submission) of the directional insert.

CLINICAL STUDIES

In the following section the studies were generated using the Tandem-R Ostase Assay.

Question 5: Please send a copy of the revised labeling for the File.

Answer: A copy of the revised directional insert is attached.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 28 2000

Ms. Jill Kull, RAC
Staff Regulatory Specialist
Beckman Coulter, Inc.
7330 Carroll Road
P.O. Box 269006
San Diego, California 92196-9006

Re: K994278
Trade Name: Access® Ostase® Assay
Regulatory Class: II
Product Code: CIN, JIS
Dated: March 14, 2000
Received: March 15, 2000

Dear Ms. Kull:

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 legally marketed predicate 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" (21CFR 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/dsma/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

INDICATIONS FOR USE STATEMENTS

510(k) Number (if known): ~~Not yet assigned~~ K994278

Device Name: **Access® Ostase® Assay**

Indications for Use:

Beckman Coulter, Inc's Access Ostase Assay is a paramagnetic particle, chemiluminescent immunoassay for use with the Access Immunoassay System for the quantitative measurement of bone alkaline phosphatase (BAP), an indicator of osteoblastic activity, in human serum and plasma. This device is intended to be used as an aid in the management of postmenopausal osteoporosis and Paget's disease.

21 CFR 862.1050 Alkaline Phosphatase or isoenzymes test system

(a) *Identification.* An alkaline phosphatase or isoenzymes test system is a device intended to measure alkaline phosphatase or its isoenzymes (a group of enzymes with similar biological activity) in serum or plasma. Measurements of alkaline phosphatase or its isoenzymes are used in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases.

(b) *Classification.* Class II.

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K994278

(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