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**510(k) Summary for
OPUS Bone ALP**

JAN 24 1997

1. Manufactures Name, Address, Telephone, and contact person, date of preparation:

Manufacturer: Behring Diagnostics Inc.
151 University Avenue
Westwood, MA 02090
617-320-3117
Attn: Ruth Forstadt

Preparation date: November 26, 1996

2. Device Name/ Classification:

OPUS Bone ALP: Alkaline Phosphatase or Isoenzmes Test System
Classification Number: Class II (862.1050)

3. Identification of the legally marketed device:

Hybritech Tandem-R Ostase

4. Proposed Device Description:

OPUS Bone ALP is a set of reagents intended to be used together with the OPUS immunoassay analyzers for the quantitative measurement of bone alkaline phosphatase (bone ALP) in human serum.

5. Proposed Device Intended Use:

OPUS Bone ALP is an *in vitro* fluorogenic enzyme immunoassay (ELISA) for the quantitative measurement of bone alkaline phosphatase (bone ALP) in human serum as an aid in the management of patients with diagnosed Paget's disease. OPUS Bone ALP is intended for use with the OPUS analyzers.

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6. Medical device to which equivalence is claimed and comparison information:

The OPUS Bone ALP assay is substantially equivalent in intended use to results obtained using the Hybritech Tandem-R Ostase. The Hybritech Tandem-R Ostase, like the proposed product, employs the principle of two site or sandwich immunoassay. Both use a labeled antibody for the quantitative measurement of bone ALP in human serum. The OPUS Bone ALP and the Hybritech Tandem-R Ostase are based on a six level calibrator system.

The OPUS Bone ALP differs from the Hybritech Tandem-R Ostase in that the mouse monoclonal antibody is labeled with 125 I in the Hybritech Tandem-R Ostase, while the enzyme labeled antibody is a mouse monoclonal in the OPUS Bone ALP test. Also, the OPUS Bone ALP includes a tri-level control, where as the Hybritech Tandem-R Ostase test includes a bi-level control. Additionally, the OPUS Bone ALP is used with a fully automated fluorometric instrument system, while the Hybritech Tandem-R Ostase uses a gamma counter.

7. Proposed Device Performance Characteristics:

Precision

Intra-assay precision was determined by the evaluation of three levels of control material in replicates of twenty (20) each. %CV ranged from 2.7% to 5.23%.

Inter-assay precision was determined by the evaluation of three levels of control material in duplicate, assayed over a five day period to total 20 replicates. %CV ranged from 4.57% to 7.06%.

Accuracy by Recovery

Recovery was determined by making four dilutions of an elevated Bone AP patient sample into a normal human serum pool. The samples were assayed using OPUS Bone ALP in duplicate. Percent recovery ranged from 98% to 103%

Accuracy by Correlation

OPUS Bone ALP was compared to a commercially available immunoassay by evaluation of 50 serum samples ranging from 5.83 to 115 ng/ml. A correlation coefficient of 0.992 was obtained with a y-intercept value of 0.77 and a slope of 1.06.

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