

**SECTION X: SUMMARY OF SAFETY AND EFFECTIVENESS FOR  
THE TANDEM-MP OSTASE ASSAY**

Tandem-MP Ostase is an *in vitro* device for the quantitative measurement of skeletal alkaline phosphatase (sALP) in human serum. The assay is a solid-phase, immunoenzymetric assay. Serum samples containing sALP are reacted in a microwell with the biotinylated capture antibody. Following binding of the biotinylated antibody/antigen complex to the streptavidin coated wells, the microwells are washed and incubated with an enzyme substrate. The captured sALP enzyme turns over the substrate and the amount of sALP bound to the microwell is determined colorimetrically by measuring the absorbance of the quenched reaction at 405 nm in a microplate reader. The calculation of the sALP concentration in the sample is based on concurrent testing of the Ostase Calibrators and Zero/Diluent.

This premarket notification has demonstrated that the Tandem-MP Ostase Immunoenzymetric Assay for the quantitative measurement of skeletal alkaline phosphatase to be used as an aid in the management of postmenopausal osteoporosis and Paget's disease is substantially equivalent to the Tandem-R Ostase Immunoradiometric Assay that was cleared by FDA in a previous submission (#K961573).

The Safe Medical Devices Act of 1990 states that a device is substantially equivalent to its predicate if they have the same technological characteristics and the same intended use. The Tandem-MP Ostase device that is the subject of this submission has technological characteristics that are the same as those of the predicate device.

The intended use of Tandem-MP Ostase remains unchanged from the predicate with regard to the analyte being measured (skeletal alkaline phosphatase) and the specimen matrix (human serum). Therefore, it has been demonstrated in this submission that the Tandem-MP Ostase assay is substantially equivalent to the predicate device and is safe and effective as an aid in the management of postmenopausal osteoporosis and Paget's disease.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

SEP 11 1997

Gregory P. Payne, RAC  
Principal Regulatory Specialist  
Hybritech, Inc.  
8958 Terman Court  
San Diego, California 92121

Re: K972666  
Tandem-MP Ostase™ Immunoenzymetric Assay  
Regulatory Class: II  
Product Code: CIN  
Dated: July 16, 1997  
Received: July 16, 1997

Dear Mr. Payne:

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.

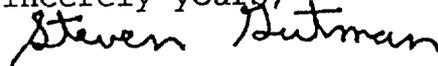
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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

**SECTION II: INDICATION FOR USE**

The Tandem-MP Ostase Immunoenzymetric Assay is an *in vitro* device indicated for the quantitative measurement of skeletal alkaline phosphatase (sALP), an indicator of osteoblastic activity, in human serum. This device is intended to be used as an aid in the management of postmenopausal osteoporosis and Paget's disease.

  
(Division Sign-Off)  
Division of Clinical Laboratory Services  
510(k) Number 12972666

Prescription Use