

V. SUMMARY OF SAFETY AND EFFECTIVENESS FOR THE TANDEM-R  
OSTASE ASSAY

Tandem®-R Ostase® is an *in vitro* device for the quantitative measurement of skeletal alkaline phosphatase (sALP) in human serum. The assay is a solid-phase, two-site immunoradiometric assay. Samples containing sALP are reacted with a plastic bead (solid phase) that is coated with a monoclonal antibody directed toward a specific site on the sALP molecule and, simultaneously, with a second radiolabeled monoclonal antibody directed toward a different antigenic site on the sALP molecule. Following formation of the solid-phase/sALP/radiolabeled antibody sandwich, the bead is washed to remove unbound labeled antibody. The radioactivity bound to the solid phase is measured in a gamma counter. The amount of radioactivity measured is directly proportional to the concentration of sALP in the test sample, which is determined from a standard curve. The standard curve is based on the concurrent testing of Tandem-R Ostase calibrators ranging from 0 to 120  $\mu\text{g}$  sALP/L.

This premarket notification has demonstrated that the Tandem-R Ostase Immunoradiometric Assay for the quantitative measurement of skeletal alkaline phosphatase (sALP), an indicator of osteoblastic activity, in human serum is substantially equivalent to the Tandem-R

Ostase assay that was cleared by FDA in a previous submission (#K930810). This premarket notification includes clinical data demonstrating that the Tandem-R Ostase assay provides the clinician with information that is of value in the management of patients with postmenopausal osteoporosis and Paget's disease.

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 intended use. The Tandem-R Ostase device that is the subject of this submission has technological characteristics that are identical to those of the predicate device. The components, manufacture, specifications, and procedure for the Tandem-R Ostase assay remain unchanged from those of the previously-cleared device (#K930810).

The intended use of Tandem-R Ostase remains unchanged from the predicate with respect to the analyte being measured (skeletal alkaline phosphatase) and the specimen matrix (human serum). The only change in the intended use is in the indication for the device. It has been demonstrated in this premarket notification that Paget's disease of bone and postmenopausal osteoporosis are both bone disorders in which patients undergoing therapy can be managed with the aid of Tandem-R Ostase.

Therefore, it has been demonstrated that the new indication for Tandem-R Ostase, as an indicator of osteoblastic activity which is intended to be used as an aid in the management of postmenopausal osteoporosis and Paget's disease, is substantially equivalent to the indication for the predicate device as an aid in the management of patients with diagnosed Paget's disease. No new issues of safety or effectiveness are raised by the change in indication for use. The Tandem-R Ostase assay remains both safe and effective when used as indicated in the product labeling.