

X: 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

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The PERCEPTOR® Compensator MORSE® Manifold, like its predicates, the MORSE® DT Manifold and the Stand Alone Transducer, is a physiological blood pressure transducer. Both devices are intended for invasive pressure monitoring, catheterization procedures, fluid delivery and/or blood access maintenance.

Both devices are expected to conform to Specifications outlined in ANSI/AAMI BP22-1994 "Blood Pressure Transducers" which is a Revision/combination of ANSI/AAMI BP22-1986 and ANSI/AAMI BP23-1986.

Biocompatibility testing has been performed on the predicate devices, there are no changes in device material.

These devices are manufactured from identical materials and function based under the same design principles which are: 1) A device which integrates a physiological pressure transducer directly into the side port lumen of a manifold. 2) A catheter provides a fluid column which communicates pressure in the heart from the tip of the catheter to the transducer. The gel acts as a vibratory membrane, allowing the signal to be passed to the sensor. The signal is communicated to the monitor via the cable.

The difference between the Compensator MORSE® Manifold and its predicates is that the lumen of the Compensator has been redirected so that it is present above and below the sensor. This allows for the following: 1) Accurate zero balancing and 2) pressure monitoring at any transducer height. Secondly, the use of an Over Pressure Protection Band has been discontinued.