

**Section I****510(k) Summary  
Required by 21 CFR §807.92**

MAY 12 1997

**I. Submitter:**

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**II. Date of preparation of this Summary: February 10, 1997****III. Trade Name: Medisystems Transducer Protectors****IV. Common Name: Transducer Protectors****V. Classification Name: Hemodialysis System and Accessories****VI. The Marketed Device(s) to which Equivalence is Claimed: The Transducer Protectors which are the subject of this submission are substantially equivalent to those described in Medisystems' 510(k) number K895856.****VII. Product Description: Medisystems Transducer Protectors are designed to be used as protective devices for pressure monitors as well as to help maintain the sterility of the blood tubing fluid pathway. The 0.2  $\mu$ m hydrophobic filter helps prevent cross-contamination by bacteria and particulate matter while preventing the flow of fluids to the machine pressure monitor at pressures less than 600 mmHg.****VIII. Statement of Intended Use Compared to Predicate Device: Medisystems Transducer Protectors are single use, disposable prescription devices intended for use as protective devices for pressure monitors and to help protect the sterility of the fluid pathway. This is identical to the intended use of the legally marketed predicate device.****IX. Discussion of Technological Characteristics: The technical characteristics of the device consist of a filter housing that contains a 0.2  $\mu$ m hydrophobic filter. Due to the pore size of the**

filter, bacteria and particulate contamination are prevented from passing from the machine pressure monitor to the blood tubing set. The combination of the pore size and hydrophobic nature of the filter also prevents the flow of fluids, bacteria, and particulate matter into the pressure monitor at pressure lower than the rated pressure of the device.

X. Safety and Effectiveness: To assure that the device is safe and effective, all finished products are tested and must meet all required release specifications before distribution. The testing required for release includes, but is not limited to; sterility, pyrogenicity, physical testing, and visual examination of both in-process and finished product.

The required testing is defined by written and approved procedures that conform to the product design specifications. This testing for the Medisystems Transducer Protectors is defined in detail in the "Device Master Records."