

**Section [2] 510(k) Summary**

K962700

APR - 9 1997

**Device Name:**

Ventraflo Blood Flow Monitoring Probe Kits

**Predicate Devices:**

The Ventricular Catheter/Probe kits are substantially equivalent to products currently in commercial distribution. Specifically, for the laser Doppler Probe the Vasamedics' model SUPR-434 Single use Blunt Needle Probe, K951832, for kit accessories and ventricular catheter the PS Medical "Becker Ventricular Catheter" and the "PS Medical Ventriculostomy Kit".

**Device Description:**

The Model BPM<sup>2</sup> is a Laser Doppler Blood Perfusion Monitor, which is used to measure microcirculatory blood flow in a variety of clinical applications. Permission to market the BPM<sup>2</sup> was granted by FDA on February 13, 1990 (Ref. K896515). The Model SUPR-434 Blunt Needle Probe is a single use fiber optic probe designed for use with the BPM<sup>2</sup>. These probes are labeled so as to be used for monitoring buried tissue, such as brain parenchyma during and following neurosurgical procedures. Permission to market the Model SUPR-434 ( Note: the SUPR-434 Blunt needle probes model names have since been changed to Trimflo 4314, 4316, 4364 and 4366) was granted on March 21, 1996 (Ref. K951832).

The Ventraflo Catheter/Probe is a standard ventricular catheter with a laser Doppler blood perfusion probe embedded into the side wall of the Catheter. So when the catheter is placed within a brain ventricle the clinician will be able to use the catheter as a CSF drain<sup>1</sup>, measure intracranial ventricular pressure, If connected to an external transducer and measure parenchymal blood flow simultaneously.

**Intended Use:**

The probes kits are intended for extravascular monitoring of microcirculation blood flow in buried tissues, specifically, in monitoring cerebral blood flow in patients at risk of cerebral ischemia.

**Biocompatibility:**

Materials used in the Probe kits that may come in contact with tissue are all biocompatible. The blood flow probe embedded into the ventricular catheter is equivalent to the Vasamedics SUPR-434 (Trimflo) probes outlined in K951832. The ventricular catheter is made of biocompatible silicone and all accessories contained in the kit are standard items used in neurosurgery and ICP monitoring.

The Probe kits will be sterilized by gas ( ETO ) sterilization methods. The cycle used will be validated in accordance with AAMI guidelines using the overkill method to a sterility assurance level (SAL) of at least  $1 \times 10^{-6}$ . Process release will be a combination of biological testing by methods at least as stringent as those described in the USP XXII monograph for sterility testing, combined with process documents review assuring that

validating conditions are met. At the time of release all residual levels will be at or below those issued in the 1978 FDA guidelines for invasive devices:

EO - 25ppm  
ECH - 25ppm  
EG - 250ppm

**Substantial Equivalence:**

The probes used in the Ventraflo Ventricular Catheter Probe kits are substantially equivalent to the following products currently in commercial distribution:

The laser Doppler probe embedded into the ventricular catheter is equivalent to the Vasamedics' model SUPR-434 Single use Blunt Needle Probe, K951832.

The kit accessories and ventricular catheter are equivalent to components in the currently marketed PS Medical "Becker Ventricular Catheter" and the "PS Medical Ventriculostomy Kit".

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April 8, 1996