

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

OCT 11 1996

**Device Name:**

Trimflo Parenchymal Blood Flow Monitoring Probe Kit

**Predicate Device:**

The Vasamedics' model SUPR-434 Single use Blunt Needle Probe, K951832 and for kit accessories the Codman disposable ICP system (believed to be a pre-amendment device).

**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).

**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 probes used in the kits are the same devices as the SUPR-434 (Trimflo) probes outlined in K951832. 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 Single Use Probe kits are substantially equivalent to products currently in commercial distribution, specifically the Model SUPR-434 (Trimflo) Single use Blunt Needle Probes. The only changes made to the product are the addition of probe accessories and the use of a tray for kit packaging. The single use probe kits will be packaged and ETO sterilized prior to shipment and will be labeled for single use only. All other kit components are equivalent to the Codman ICP monitoring kit.

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