

K951832

## Section [2] 510(k) Summary

### Device Name:

Laserflo Blood perfusion Single Use Probes Models SUP-440, SUPR-434, SUP-433

### Predicate Device:

The SUP- 440, SUPR-434 and the SUP- 433 are accessories to the Vasmedics' BPM<sup>2</sup> Blood perfusion Monitor, K896515 and equivalent to the Vasamedics' Model P-433 Needle Probe, K875179, the Model PR-434 Implantable Prism Probe, K875179, and the P-440 Soflex Probe, K912446.

### 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 P-433 Needle Probe, Model PR-434 Implantable Prism Probe, and Model P-440 Implantable Soflex Probe are fiber optic probes designed for use with the BPM<sup>2</sup>. These probes are labelled so as to be used for monitoring buried tissue, such as buried muscle following free muscle transfers and cerebral cortex following neurosurgical procedures. Permission to market the Model PR-434 and Model P-433 probes was granted by FDA on September 19, 1988 (Ref K875179). Permission to market the P-440 was granted by FDA on December 12, 1991 (Ref K912446).

The single use probes, SUP-440 Disposable Flat Profile Probe, SUP-433 Disposable Right Angle Needle Probe, and SUPR-434 Disposable Blunt End Needle probe are also fiber optic probes designed for use with the BPM<sup>2</sup>. They connect to the BPM<sup>2</sup> Probe Connector Port on the BPM<sup>2</sup> front panel via a fiber optic interface cable. The tip of the SUP-440 Disposable Flat Profile Probe is similar to the P-440 Soflex Probe in that it includes the termination of the optical fiber which provides right angle light emission, and an outer encapsulation of soft, flexible material. The tip of the SUP-433 Disposable Right Angle Needle Probe and the SUPR-434 Disposable Blunt End Needle Probe are similar to the P-433 Needle Probe in that it includes the termination of the optical fiber in a stainless steel tube and similar to the PR-434 Implantable prism probe in that the probes provide right angle light emission.

### Intended Use:

The Single Use Probes are intended for extravascular monitoring of microcirculation blood flow in buried tissues. An example of this application is the monitoring of buried muscle or esophagus following free muscle transfer or esophageal reconstruction. Another example is monitoring soft tissue microcirculation following reconstructive surgery, such as in oral and facial reconstruction. Yet another example is monitoring cerebral blood flow during and following neurosurgery for head trauma.