

K964283

CONFIDENTIAL

## Appendix B

510(k) Summary

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Trade name: AutoPrime™

Common name: I.V. Filter and set

Classification name: Infusion line filter and administration set (21 CFR 880.5440)

The Arbor Medical AutoPrime™ I.V. is as safe and effective as the 3M Health Care AVI™ Administration Set with an 0.22um filter and the Block Medical Verifuse® Administration Set with 1.2 um IV-3. All filters are intended to filter intravenous solutions.

Per FDA Safety Alert: Hazards of Precipitation Associated with Parental Nutrition, issued April 18, 1994, an IV filter is indicated for use when infusing either central or peripheral parenteral nutrition admixtures. Both pore sizes of filters are being offered, a 0.22um air eliminating filter for nonlipid containing admixtures, and a 1.2um air eliminating filter for lipid containing admixtures.

### Technological Characteristics:

1. The 0.22um filters both make a claim of passing a bacterial challenge of  $10^7$  with *Pseudomonas diminuta*, referred to as a HIMA challenge. Materials of construction are the same, both filters are made with 0.22um polyethersulfone main membranes, vent filters made with .02um PTFE and housings made from modified acrylic. Bench test data is not required due to there being no technological differences that raise issues of safety or efficacy.

2. The 1.2um filters both make a claim of retaining *Candida Albicans*. Materials of construction are the same, both filters are made with 1.2um polyethersulfone main membranes, vent filters made with .02um PTFE and housings made from blue modified acrylic. Bench test data is not required due to there being no technological differences that raise issues of safety or efficacy.