

K960928

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Appendix C

Summary of Safety and Effectiveness

The revised Arbor Medical Syringe filter is as safe and effective as the original. The proposed plastic housings and membrane have passed Class VI testing as did the original housings and membrane. The proposed product is manufactured the same as the original. The method of sterilization is the same as the original version. The intended use is the same. Testing for both the original and the proposed versions of this filter are the same. Both versions of the 0.2um have passed the HIMA Challenge.