



MERCURY
M E D I C A L[®]

K954490

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REVISED

ENCLOSURE E

SMDA SUMMARY

K954490

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act 1990 and 21 CFR 897.92. This device is the combination of two previously cleared devices: the Mercury Medical CPR Resuscitator (K911622) with Filter manufactured by Medicomp (K851070), which has been subsequently tested and supported with independent laboratory data for BFE and VFE. This would be consistent with the application of the Intertech/Inspiron Resuscitation Bag Filter (K883693) and Westmed (K951484) and (K953687).

- Product Name - Mercury CPR Bag with Filter
- Common Name - Resuscitation Bag Filter
- Classification Name - Filter, Bacterial, Breathing Circuits

Arthur J. Ward

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October 2, 1996

Date