

Premarket Approval (PMA) Package for
Dockets Management Branch

PMA Number P010041
Docket # 2003M-0086

Edwards Lifesciences LLC
Carpentier-Edwards S.A.V. Bioprosthesis,
Model 2650 (Aortic)

Includes:

Approval Order
Summary of Safety and Effectiveness Data (SSED)
Labeling

2003M-0086

CR 1