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510(k) Premarket Notification Database

Device Classification Name	Catheter, Intravascular, Diagnostic
510(K) Number	K034043
Device Name	H-FLOW VALVE
Applicant	ELCAM MEDICAL A.C.A.L. Kibbutz Bar-Am D.N. Merom Hagalil, IS 13860
Contact	Tali Hazan
Regulation Number	870.1200
Classification Product Code	DQO
Date Received	12/29/2003
Decision Date	06/30/2004
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Cardiovascular
Review Advisory Committee	Cardiovascular
Statement/Summary/Purged Status	Summary Only
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No

Database Updated 08/06/2008

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