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510(k) Premarket Notification Database

Device Classification Name	Thermometer, Electronic, Clinical
510(K) Number	K033790
Regulation Number	880.2910
Device Name	THERMOFOCUS 0800, 0900, 01500 AND 0700 SERIES TECNIMED S.R.L.
Applicant	55 Northern Blvd. Suite 200 Great Neck, NY 11021
Contact	Carolann Kotula
Classification Product Code	FLL
Date Received	12/05/2003
Decision Date	06/03/2004
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	General Hospital
Review Advisory Committee	General Hospital
Statement/Summary/Purged Status	Summary Only
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No

Database Updated 6/06/2005

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