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510(k) Premarket Notification Database

Device Classification Name	Lamp, Infrared, Therapeutic Heating
510(K) Number	K030275
Device Name	MB SYSTEM, BIOENERGY LIGHT THERAPY
Applicant	AMEST CORP. 30394 Esperanza Rancho Santa Margarita, CA 92688
Contact	John Iest
Regulation Number	890.5500
Classification Product Code	ILY
Date Received	01/27/2003
Decision Date	11/29/2004
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Physical Medicine
Review Advisory Committee	General & Plastic Surgery
Statement/Summary/Purged Status	Summary Only
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No

Database Updated 04/07/2009