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Innovations for a healthier life



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FDA Medical Device #2954299

Device Classification Name	Pad, Heating, Powered
510(K) Number	K072534
Device Name	BIO-MAT 2000
Applicant	RICHWAY INTL., INC. 1314 South King St., Suite 520 Honolulu, HI 96814
Contact	Leroy Klima
Regulation Number	890.5740
Classification Product Code	IRT
Date Received	09/07/2007
Decision Date	02/08/2008
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Physical Medicine
Review Advisory Committee	Physical Medicine
Statement/Summary/Purged Status	Summary Only
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No