

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