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510(k) Premarket Notification Database

Device Classification Name	Table, Physical Therapy, Multi Function
510(K) Number	K041200
Regulation Number	890.5880
Device Name	THERMASSAGE ENEGRY PRODUCT, MODEL HY-7000
Applicant	MIGUN MEDICAL INSTRUMENT CO. LTD. 5905 Fawn Lane Cleveland, OH 44141
Contact	Edward A Kroll
Product Code	JFB
Date Received	05/07/2004
Device Name	THERMASSAGE ENEGRY PRODUCT, MODEL HY-7000
Applicant	MIGUN MEDICAL INSTRUMENT CO. LTD. 5905 Fawn Lane Cleveland, OH 44141
Contact	Edward A Kroll
Product Code	JFB
Date Received	05/07/2004
Decision Date	06/17/2004
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Physical Medicine
Review Advisory Committee	Physical Medicine
Statement/Summary/Purged Status	Statement Only
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No

Database Updated 7/06/2004