



510(k) Premarket Notification Database

Device Classification Name	Lamp, Non-Heating, For Adjunctive Use In Pain Therapy
510(K) Number	K034009
Device Name	LAPEX 2000
Applicant	MERIDIAN CO., LTD. Po Box 7007 Deerfield, IL 60015
Contact	Daniel Kamm
Regulation Number	890.5500
Classification Product Code	NHN
Date Received	12/29/2003
Decision Date	01/21/2005
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Physical Medicine
Review Advisory Committee	General & Plastic Surgery
Statement/Summary/Purged Status	Summary Only
Summary	Summary
Type	Abbreviated
Reviewed By Third Party	No
Expedited Review	No