510(k) Premarket Notification

Device Classification Name	System, Nuclear Magnetic Resonance Imaging[22]
510(K) Number	K003573
Device Name	DIFFUSION TENSOR IMAGING OPTION
Applicant	GE MEDICAL SYSTEMS, INC. P.O. BOX 414 Milwaukee, WI 53201
Applicant Contact	Larry A Kroger
Correspondent	GE MEDICAL SYSTEMS, INC. P.O. BOX 414 Milwaukee, WI 53201
Correspondent Contact	Larry A Kroger
Regulation Number	892.1000[23]
Classification Product Code	LNH[24]
Date Received	11/20/2000
Decision Date	01/23/2001
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Radiology
510k Review Panel	Radiology
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

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