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510(k) Premarket Notification Database

Device Classification Name	Camera, Ophthalmic, Ac-Powered
510(K) Number	K062416
Device Name	RETINAL FUNCTIONAL IMAGER (RFI)
Applicant	OPTICAL IMAGING LTD. 555 Thirteenth St. Nw Washington, DC 20004
Contact	Jonathan S Kahan
Regulation Number	886.1120
Classification Product Code	HKI
Subsequent Product Code	HLI
Date Received	08/17/2006
Decision Date	11/17/2006
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Ophthalmic
Review Advisory Committee	Ophthalmic
Statement/Summary/Purged Status	Summary Only
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No

Database Updated 06/06/2008