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510(k) Premarket Notification



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|--|---|
| Device Classification Name | Camera, Ophthalmic, Ac-Powered |
| 510(K) Number | K080180 |
| Device Name | MODIFICATION TO RETINAL FUNCTION 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 |
| Date Received | 01/24/2008 |
| Decision Date | 06/11/2008 |
| 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 |