

**K971685 IMAGESCAPE DIGITAL RETINAL IMAGE SYSTEM**Jun 24, 1997  
48 days to decisionK971685 · Product code: **HKI** · Ophthalmic  
Source: <https://www.510kdatabase.net/k971685/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	May 7, 1997
Decision date	Jun 24, 1997
Days to decision	48 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tomey Corporation USA</b>
Location	Cambridge, MA, US
Contact	HOWARD M HOLSTEIN
510(k) history	9 submissions · 9 cleared · 1991-1997

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