

K081797 IMAGE STORAGE SYSTEM, MODEL KSS-400Jan 22, 2009
211 days to decisionK081797 · Product code: **NFJ** · Ophthalmic
Source: <https://www.510kdatabase.net/k081797/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Management, Ophthalmic (NFJ)
Date received	Jun 25, 2008
Decision date	Jan 22, 2009
Days to decision	211 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Konan Medical, Inc.
Location	Hyogo, JP
Contact	GEORGE MYERS
510(k) history	7 submissions · 7 cleared · 1995-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k081797/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026