

**K011877 FF450 PLUS FUNDUS CAMERA AND VISUPAC
DIGITAL IMAGE ARCHIVING SYSTEM, OR FF450 PLUS
VISUPAC SYSTEM**Sep 26, 2001
103 days to decisionK011877 · Product code: **HKI** · Ophthalmic
Source: <https://www.510kdatabase.net/k011877/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Jun 15, 2001
Decision date	Sep 26, 2001
Days to decision	103 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Carl Zeiss Jena GmbH
Location	Washington, DC, US
Contact	JONATHAN S KAHAN
510(k) history	1 submissions · 1 cleared · 2001-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k011877/>. 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 June 29, 2026