FDA 510(k) Premarket Notification

K082196 STATIC VESSEL ANALYZER

CLEARED

Jun 16, 2009
316 days to decision

K082196 · Product code: **HKI** · Ophthalmic
Source: https://www.510kdatabase.net/k082196/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Aug 4, 2008
Decision date	Jun 16, 2009
Days to decision	316 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Imedos GmbH**
Location	League City, TX, US
Contact	HANS STROMEYER
510(k) history	1 submissions · 1 cleared · 2009-2009