FDA 510(k) Premarket Notification

K812764 KOI BLUE FIELD ENTOPTOSCOPE

CLEARED

Dec 2, 1981
61 days to decision

K812764 · Product code: **HKL** · Ophthalmic
Source: https://www.510kdatabase.net/k812764/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Retinoscope, Ac-powered (HKL)
Date received	Oct 2, 1981
Decision date	Dec 1, 1981
Days to decision	61 days
Third-party review	No

APPLICANT

Company	**Koi, Inc.**
Location	Mchenry, IL, US
510(k) history	7 submissions · 7 cleared · 1981-1986