FDA 510(k) Premarket Notification

K013805 KOWA AUTOMATED TONOMETER KT-500

CLEARED

Oct 11, 2002
330 days to decision

K013805 · Product code: **HKX** · Ophthalmic
Source: https://www.510kdatabase.net/k013805/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tonometer, Ac-powered (HKX)
Date received	Nov 15, 2001
Decision date	Oct 11, 2002
Days to decision	330 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Kowa Optimed, Inc.**
Location	Torrance, CA, US
Contact	FRANCES K WU
510(k) history	10 submissions · 10 cleared · 1988-2002