FDA 510(k) Premarket Notification

K133234 T-TYPE D-KAT, R-TYPE D-KAT

CLEARED

Feb 21, 2014
123 days to decision

K133234 · Product code: **HKY** · Ophthalmic
Source: https://www.510kdatabase.net/k133234/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tonometer, Manual (HKY)
Date received	Oct 21, 2013
Decision date	Feb 21, 2014
Days to decision	123 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Keeler Limited**
Location	Broomall, PA, US
Contact	EUGENE R VANARSDALE
510(k) history	5 submissions · 5 cleared · 2014-2015