FDA 510(k) Premarket Notification

K131719 OPHTHALMOSCOPES DIAGNOSTIC INSTRUMENT KITS

CLEARED

Oct 30, 2013
140 days to decision

K131719 · Product code: **HLJ** · Ophthalmic
Source: https://www.510kdatabase.net/k131719/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ophthalmoscope, Battery-powered (HLJ)
Date received	Jun 12, 2013
Decision date	Oct 30, 2013
Days to decision	140 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Medical Devices (Pvt) , Ltd.**
Location	Ugoki-Sialkot, PK
Contact	TAUSEEF AJMAL
510(k) history	1 submissions · 1 cleared · 2013-2013

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k131719/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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