FDA 510(k) Premarket Notification

K133562 CATARHEX 3

CLEARED

Aug 12, 2014
265 days to decision

K133562 · Product code: **HQC** · Ophthalmic
Source: https://www.510kdatabase.net/k133562/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Phacofragmentation (HQC)
Date received	Nov 20, 2013
Decision date	Aug 12, 2014
Days to decision	265 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Oertli Instrumente AG**
Location	Berneck, CH
Contact	KARIN ROHR
510(k) history	2 submissions · 2 cleared · 2014-2024