

K131961 HEINE BETA 200(R) OPHTHALMOSCOPEDec 4, 2013
160 days to decisionK131961 · Product code: **HLJ** · Ophthalmic
Source: <https://www.510kdatabase.net/k131961/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Ophthalmoscope, Battery-powered (HLJ)
Date received	Jun 27, 2013
Decision date	Dec 4, 2013
Days to decision	160 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Heine Optotechnik GmbH & Co. KG
Location	Hamburg, DE
Contact	MANFRED BARTSCH-TITTMANN
510(k) history	7 submissions · 7 cleared · 2010-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k131961/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 4, 2026