

K040204 ZYOPTIX XP MICROKERATOMEMar 22, 2004
53 days to decisionK040204 · Product code: **HNO** · Ophthalmic
Source: <https://www.510kdatabase.net/k040204/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Keratome, Ac-powered (HNO)
Date received	Jan 29, 2004
Decision date	Mar 22, 2004
Days to decision	53 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bausch & Lomb, Inc.
Location	Mchenry, IL, US
Contact	DEBRA L.B. KETCHUM
Website	http://www.bausch.com
510(k) history	92 submissions · 92 cleared · 1977-2019

Bausch & Lomb, Inc. is a Canadian eye health company founded in 1853. The company is now part of Valeant Pharmaceuticals following a 2013 acquisition. Bausch & Lomb has received FDA 510(k) clearances from total submissions since 1977. The company specializes in Ophthalmic devices, which represent 83% of its regulatory submissions. Recent cleared devices include contact lenses, intraocular lens injectors, lens delivery systems, and care solutions. The company's last FDA 510(k) clearance was in 2019, and this profile reflects its historical regulatory record. Bausch & Lomb ...
