FDA 510(k) Premarket Notification

# K021640 HANSATOME EXCELLUS MICROKERATOME

**CLEARED**

Jun 19, 2002
30 days to decision

K021640 · Product code: **HNO** · Ophthalmic
Source: https://www.510kdatabase.net/k021640/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Keratome, Ac-powered (HNO) |
| Date received | May 20, 2002 |
| Decision date | Jun 19, 2002 |
| Days to decision | 30 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Bausch & Lomb, Inc.** |
| Location | Mchenry, IL, US |
| Contact | DENNIS POZZO |
| 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 ...