FDA 510(k) Premarket Notification

# K935561 INTERPLAK HOME PLAQUE REMOVAL INSTRUMENT

**CLEARED**

Jan 26, 1994
70 days to decision

K935561 · Product code: **JEQ** · Dental
Source: https://www.510kdatabase.net/k935561/

**SUBMISSION DETAILS**

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Toothbrush, Powered (JEQ) |
| Date received | Nov 17, 1993 |
| Decision date | Jan 26, 1994 |
| Days to decision | 70 days |
| Third-party review | No |
| Summary / Statement | Statement |

**APPLICANT**

| | |
|---|---|
| Company | **Bausch & Lomb, Inc.** |
| Location | Mchenry, IL, US |
| Contact | SYDNEY LILLY |
| 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 ...