FDA 510(k) Premarket Notification

K921999 INTERJET(TM) GINGIVAL CARE INSTRUMENT

CLEARED

Jun 3, 1992
35 days to decision

K921999 · Product code: **EFS** · Dental
Source: https://www.510kdatabase.net/k921999/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Oral Irrigation (EFS)
Date received	Apr 29, 1992
Decision date	Jun 3, 1992
Days to decision	35 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bausch & Lomb, Inc.**
Location	Mchenry, IL, US
Contact	STEPHENS
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 ...