FDA 510(k) Premarket Notification

K850709 SPECTRONIC 501 & 601 - CLINICAL SPECTROPHOTOMETER

CLEARED

Mar 12, 1985
18 days to decision

K850709 · Product code: **JJQ** · Chemistry
Source: https://www.510kdatabase.net/k850709/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colorimeter, Photometer, Spectrophotometer For Clinical Use (JJQ)
Date received	Feb 22, 1985
Decision date	Mar 12, 1985
Days to decision	18 days
Third-party review	No

APPLICANT

Company	**Bausch & Lomb, Inc.**
Location	Mchenry, IL, US
Contact	NICHOLAS A WALP
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 ...