

K854159 ELLIPTI-PUNCHNov 15, 1985
35 days to decisionK854159 · Product code: **FZI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k854159/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Apparatus, Air Handling, Enclosure (FZI)
Date received	Oct 11, 1985
Decision date	Nov 15, 1985
Days to decision	35 days
Third-party review	No

APPLICANT

Company	Alcon Laboratories
Location	Mchenry, IL, US
Contact	REBECCA G WALKER
Website	https://www.alcon.com
510(k) history	47 submissions · 47 cleared · 1976-2007

Alcon Laboratories is a Swiss-American pharmaceutical and medical device company specializing in eye care products. The company maintains operational headquarters in Fort Worth, Texas, with a significant global presence in eye care innovation. Alcon has received FDA 510(k) clearances from total submissions since its first clearance in 1976. The company's regulatory portfolio is dominated by Ophthalmic devices, which account for 74% of all submissions. The latest clearance on record dates to 2007, reflecting the company's historical significance in the medical device regul...

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k854159/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 26, 2026