FDA 510(k) Premarket Notification

K862564 A.C.L. GUIDE KIT

CLEARED

Aug 18, 1986
46 days to decision

K862564 · Product code: **FZX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k862564/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Guide, Surgical, Instrument (FZX)
Date received	Jul 3, 1986
Decision date	Aug 18, 1986
Days to decision	46 days
Third-party review	No

APPLICANT

Company	**Aspen Laboratories, Inc.**
Location	Mchenry, IL, US
Contact	JOHNSON
510(k) history	55 submissions · 55 cleared · 1976-1998