FDA 510(k) Premarket Notification

K951194 FI-10M

CLEARED

Apr 6, 1995
21 days to decision

K951194 · Product code: **CAL** · Anesthesiology
Source: https://www.510kdatabase.net/k951194/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laryngoscope, Non-rigid (CAL)
Date received	Mar 16, 1995
Decision date	Apr 6, 1995
Days to decision	21 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Pentax Precision Instrument Corp.**
Location	Mchenry, IL, US
Contact	PAUL SILVA
510(k) history	67 submissions · 67 cleared · 1979-2004