FDA 510(k) Premarket Notification

K934696 ANGIOSCOPE

CLEARED

Jan 18, 1994
110 days to decision

K934696 · Product code: **LYK** · Cardiovascular
Source: https://www.510kdatabase.net/k934696/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Angioscope (LYK)
Date received	Sep 30, 1993
Decision date	Jan 18, 1994
Days to decision	110 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Intramed Laboratories, Inc.**
Location	San Diego, CA, US
Contact	STEPHEN A SOSNOWSKI
510(k) history	14 submissions · 14 cleared · 1987-1996