FDA 510(k) Premarket Notification

K011793 KSEA FIBERSCOPE

CLEARED

Apr 17, 2002
313 days to decision

K011793 · Product code: **LYK** · Cardiovascular
Source: https://www.510kdatabase.net/k011793/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Angioscope (LYK)
Date received	Jun 8, 2001
Decision date	Apr 17, 2002
Days to decision	313 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**KARL STORZ Endoscopy-America, Inc.**
Location	Mchenry, IL, US
Contact	JAMES A LEE
510(k) history	361 submissions · 361 cleared · 1980-2024