FDA 510(k) Premarket Notification

K905083 4.5F IMAGECATH ANGIOSCOPE

CLEARED

Jun 21, 1991
220 days to decision

K905083 · Product code: **LYK** · Cardiovascular
Source: https://www.510kdatabase.net/k905083/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Angioscope (LYK)
Date received	Nov 13, 1990
Decision date	Jun 21, 1991
Days to decision	220 days
Third-party review	No

APPLICANT

Company	**Baxter Healthcare Corp**
Location	Mchenry, IL, US
Contact	RONALD H BERGESON
510(k) history	505 submissions · 496 cleared · 1977-2019

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k905083/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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