FDA 510(k) Premarket Notification

K910204 SWAN-GANZ(R) HI-SHORE(R) THERMO CATH W/AMC(TM)

CLEARED

Apr 24, 1991
98 days to decision

K910204 · Product code: **DQO** · Cardiovascular
Source: https://www.510kdatabase.net/k910204/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Jan 16, 1991
Decision date	Apr 24, 1991
Days to decision	98 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k910204/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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