FDA 510(k) Premarket Notification

K905458 SWAN-GANZ(R) FLOW DIRECT OXIMETRY/THERMOD CATHER

CLEARED

Feb 7, 1991
64 days to decision

K905458 · Product code: **DQE** · Cardiovascular
Source: https://www.510kdatabase.net/k905458/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Oximeter, Fiber-optic (DQE)
Date received	Dec 5, 1990
Decision date	Feb 7, 1991
Days to decision	64 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k905458/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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