FDA 510(k) Premarket Notification

K802481 7FRENCH FLOW DIRECTED TRIPLE LUMEN CATH

CLEARED

Oct 31, 1980
24 days to decision

K802481 · Product code: **DYG** · Cardiovascular
Source: https://www.510kdatabase.net/k802481/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Flow Directed (DYG)
Date received	Oct 7, 1980
Decision date	Oct 31, 1980
Days to decision	24 days
Third-party review	No

APPLICANT

Company	**Waters Assoc., Inc.**
Location	Mchenry, IL, US
510(k) history	16 submissions · 16 cleared · 1976-1981