FDA 510(k) Premarket Notification

K832380 PROTECTIVE SLEEVE

CLEARED

Nov 28, 1983
132 days to decision

K832380 · Product code: **DYG** · Cardiovascular
Source: https://www.510kdatabase.net/k832380/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Flow Directed (DYG)
Date received	Jul 19, 1983
Decision date	Nov 28, 1983
Days to decision	132 days
Third-party review	No

APPLICANT

Company	**Vertex Medical Corp.**
Location	Mchenry, IL, US
510(k) history	21 submissions · 21 cleared · 1982-1984