FDA 510(k) Premarket Notification

K820883 SEPTISLEEVE

CLEARED

Apr 29, 1982
30 days to decision

K820883 · Product code: **DYG** · Cardiovascular
Source: https://www.510kdatabase.net/k820883/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Flow Directed (DYG)
Date received	Mar 30, 1982
Decision date	Apr 29, 1982
Days to decision	30 days
Third-party review	No

APPLICANT

Company	**Argon Medical Corp.**
Location	Mchenry, IL, US
510(k) history	27 submissions · 27 cleared · 1976-1991