FDA 510(k) Premarket Notification

K780126 DILATOR, VESSEL & INTRODUCER, SHEATH

CLEARED

Mar 2, 1978
37 days to decision

K780126 · Product code: **DRE** · Cardiovascular
Source: https://www.510kdatabase.net/k780126/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Jan 24, 1978
Decision date	Mar 2, 1978
Days to decision	37 days
Third-party review	No

APPLICANT

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