FDA 510(k) Premarket Notification

K802327 SHEATH DILATOR SET

CLEARED

Oct 10, 1980
17 days to decision

K802327 · Product code: **DRE** · Cardiovascular
Source: https://www.510kdatabase.net/k802327/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Sep 23, 1980
Decision date	Oct 10, 1980
Days to decision	17 days
Third-party review	No

APPLICANT

Company	**Stanco Medical, Inc.**
Location	Mchenry, IL, US
510(k) history	19 submissions · 19 cleared · 1979-1981