FDA 510(k) Premarket Notification

K010913 VYGON SPLIT CANNULA INTRODUCER

CLEARED

Sep 28, 2001
185 days to decision

K010913 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k010913/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Mar 27, 2001
Decision date	Sep 28, 2001
Days to decision	185 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Vygon Corp.**
Location	East Rutherford, NJ, US
Contact	ROBERT SCHIFF
510(k) history	48 submissions · 46 cleared · 1985-2012