FDA 510(k) Premarket Notification

K921352 VYGON POLYURETHANE VENOUS/ARTERIAL XRO UMBIL. CATH

CLEARED

Oct 26, 1992
221 days to decision

K921352 · Product code: **FOS** · General Hospital
Source: https://www.510kdatabase.net/k921352/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Umbilical Artery (FOS)
Date received	Mar 19, 1992
Decision date	Oct 26, 1992
Days to decision	221 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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