FDA 510(k) Premarket Notification

K963981 VYGON BIONECTOR WITH EXTENSION SET

CLEARED

Feb 14, 1997
134 days to decision

K963981 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k963981/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Oct 3, 1996
Decision date	Feb 14, 1997
Days to decision	134 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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