FDA 510(k) Premarket Notification

K070705 MODIFICATION TO: LATEX-FREE BIONECTOR, MODEL# 896.019, 896.039

CLEARED

Nov 30, 2007
261 days to decision

K070705 · Product code: **FOZ** · General Hospital
Source: https://www.510kdatabase.net/k070705/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days (FOZ)
Date received	Mar 14, 2007
Decision date	Nov 30, 2007
Days to decision	261 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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