

K981630 VYGON DOUBLE LUMEN UMBILICAL CATHETEROct 1, 1998
147 days to decisionK981630 · Product code: **FOS** · General Hospital
Source: <https://www.510kdatabase.net/k981630/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Umbilical Artery (FOS)
Date received	May 7, 1998
Decision date	Oct 1, 1998
Days to decision	147 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Schiff & Co.
Location	West Cadwell, NJ, US
Contact	ANNE M CESARIO
510(k) history	15 submissions · 15 cleared · 1988-1999

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