

**K964665 VASCUTEK GELWEAVE VASCULAR GRAFT
(BIFURCATED CONFIGURATION)**Feb 19, 1997
90 days to decisionK964665 · Product code: **DSY** · Cardiovascular
Source: <https://www.510kdatabase.net/k964665/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - ST
Submission type	Traditional
Device classification	Prosthesis, Vascular Graft, Of 6mm And Greater Diameter (DSY)
Date received	Nov 21, 1996
Decision date	Feb 19, 1997
Days to decision	90 days
Third-party review	No

APPLICANT

Company	Carbomedics, Inc.
Location	Mchenry, IL, US
Contact	TEENA M AUGOSTINO
510(k) history	22 submissions · 18 cleared · 1979-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k964665/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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