

K191252 Gem FlowCoupler SystemJul 9, 2019
61 days to decisionK191252 · Product code: **MVR** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k191252/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Anastomotic, Microvascular (MVR)
Date received	May 9, 2019
Decision date	Jul 9, 2019
Days to decision	61 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Baxter/ Synovis Micro Companies Alliance, Inc.
Location	St. Paul, MN, US
Contact	Julie Carlston
510(k) history	2 submissions · 2 cleared · 2019-2019

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