

K213974 GEM FLOW COUPLER Monitor (GEM1020M-2)Apr 20, 2022
121 days to decisionK213974 · Product code: **DPW** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k213974/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Flowmeter, Blood, Cardiovascular (DPW)
Date received	Dec 20, 2021
Decision date	Apr 20, 2022
Days to decision	121 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Synovis Micro Companies Alliance, Inc.
Location	Birmingham, AL, US
Contact	Russell Pagano
510(k) history	4 submissions · 4 cleared · 2004-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213974/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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