

K221843 GEM Biover Microvascular ClampsSep 14, 2022
82 days to decisionK221843 · Product code: **DXC** · CardiovascularSource: <https://www.510kdatabase.net/k221843/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Clamp, Vascular (DXC) |
| Date received | Jun 24, 2022 |
| Decision date | Sep 14, 2022 |
| Days to decision | 82 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 | Julie Carlston |
| 510(k) history | 4 submissions · 4 cleared · 2004-2022 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221843/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026