

K242541 GEM ZIPCLIPJan 15, 2025
142 days to decisionK242541 · Product code: **FZP** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k242541/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Clip, Implantable (FZP) |
| Date received | Aug 26, 2024 |
| Decision date | Jan 15, 2025 |
| Days to decision | 142 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Synovis Micro Companies Alliance A Subsidiary of Baxter Int |
| Location | Birmingham, AL, US |
| Contact | Julie Carlston |
| 510(k) history | 1 submissions · 1 cleared · 2025-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242541/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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