

K201934 Surgimatix Absorbable Fixation SystemOct 1, 2021
445 days to decisionK201934 · Product code: **GDW** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k201934/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Staple, Implantable (GDW) |
| Date received | Jul 13, 2020 |
| Decision date | Oct 1, 2021 |
| Days to decision | 445 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Surgimatix, Inc. |
| Location | Elk Grove Village, IL, US |
| Contact | Dorene Markwiese |
| 510(k) history | 2 submissions · 2 cleared · 2014-2021 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201934/> 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