

K182725 ApisMay 31, 2019
245 days to decisionK182725 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k182725/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Dressing, Wound, Drug (FRO) |
| Date received | Sep 28, 2018 |
| Decision date | May 31, 2019 |
| Days to decision | 245 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Sweetbio, Inc. |
| Location | Memphis, TN, US |
| Contact | Kayla Graff |
| 510(k) history | 2 submissions · 2 cleared · 2019-2023 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182725/> 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