

K191361 DemeDIOX Barbed Absorbable Surgical SutureNov 7, 2019
170 days to decisionK191361 · Product code: **NEW** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k191361/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Suture, Surgical, Absorbable, Polydioxanone (NEW) |
| Date received | May 21, 2019 |
| Decision date | Nov 7, 2019 |
| Days to decision | 170 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Demetech Corporation |
| Location | Miami Lakes, FL, US |
| Contact | Tracy Chadwick |
| 510(k) history | 5 submissions · 5 cleared · 2018-2020 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191361/> 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 June 24, 2026