

K214070 OviTex PRS (Long Term Resorbable)Mar 21, 2023
449 days to decisionK214070 · Product code: **FTM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k214070/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Mesh, Surgical (FTM) |
| Date received | Dec 27, 2021 |
| Decision date | Mar 21, 2023 |
| Days to decision | 449 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Tela Bio |
| Location | Malvern, PA, US |
| Contact | John Urtz |
| 510(k) history | 1 submissions · 1 cleared · 2023-2023 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k214070/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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