

K241126 OviTex PRSMay 22, 2024
29 days to decisionK241126 · Product code: **FTM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k241126/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Mesh, Surgical (FTM) |
| Date received | Apr 23, 2024 |
| Decision date | May 22, 2024 |
| Days to decision | 29 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | TELA Bio, Inc. |
| Location | Malvern, PA, US |
| Contact | John Urtz |
| 510(k) history | 3 submissions · 3 cleared · 2014-2024 |

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