

**K243595 OviTex PRS (Long-Term Resorbable)**Dec 19, 2024  
29 days to decisionK243595 · Product code: **FTM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k243595/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical (FTM)
Date received	Nov 20, 2024
Decision date	Dec 19, 2024
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243595/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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