

K182493 Bovine Pericardial Tissue PatchJun 18, 2019
280 days to decisionK182493 · Product code: **FTM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k182493/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical (FTM)
Date received	Sep 11, 2018
Decision date	Jun 18, 2019
Days to decision	280 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tisgenx
Location	Irvine, CA, US
Contact	Kris Kupumbati
510(k) history	1 submissions · 1 cleared · 2019-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182493/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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