

K182259 Gentrix Surgical Matrix, Gentrix Surgical Matrix HiatalFeb 7, 2019
170 days to decisionK182259 · Product code: **FTM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k182259/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical (FTM)
Date received	Aug 21, 2018
Decision date	Feb 7, 2019
Days to decision	170 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Acell, Inc.
Location	Washington, DC, US
Contact	Andrea Artman
510(k) history	20 submissions · 20 cleared · 2002-2024

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