

K191461 Exofin Fusion Skin Closure SystemJun 5, 2020
368 days to decisionK191461 · Product code: **OMD** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k191461/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cutaneous Tissue Adhesive With Mesh (OMD)
Date received	Jun 3, 2019
Decision date	Jun 5, 2020
Days to decision	368 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Chemence Medical, Inc.
Location	Alpharetta, GA, US
Contact	Kenneth N Broadley
510(k) history	6 submissions · 6 cleared · 2006-2021

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