

K191545 Exogenesis Hernia MeshSep 26, 2019
107 days to decisionK191545 · Product code: **FTL** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k191545/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Jun 11, 2019
Decision date	Sep 26, 2019
Days to decision	107 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Exogenesis Corporation
Location	Billerica, MA, US
Contact	Joseph Khoury
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	O&apos;Connell Regulatory Consultants, Inc.
Contact	Maureen O'Connell

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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