FDA 510(k) Premarket Notification

K191545 Exogenesis Hernia Mesh

CLEARED

Sep 26, 2019
107 days to decision

K191545 · Product code: **FTL** · General & Plastic Surgery
Source: 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'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