FDA 510(k) Premarket Notification

K221556 T-Line Hernia Mesh

CLEARED

Nov 28, 2022
181 days to decision

K221556 · Product code: **FTL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k221556/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	May 31, 2022
Decision date	Nov 28, 2022
Days to decision	181 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Deep Blue Medical Advances, Inc.**
Location	Durham, NC, US
Contact	William Perry
510(k) history	4 submissions · 4 cleared · 2020-2023

REGULATORY CONSULTANT

Consulting firm	**Lincé Consulting, LLC**
Contact	Nancy Lincé

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