FDA 510(k) Premarket Notification

K221280 Vesseal

CLEARED

Dec 9, 2022
220 days to decision

K221280 · Product code: **GAW** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k221280/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Nonabsorbable, Synthetic, Polypropylene (GAW)
Date received	May 3, 2022
Decision date	Dec 9, 2022
Days to decision	220 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Lydus Medical , Ltd.**
Location	Ra'Anana, IL
Contact	Jessica Weiss
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Orly Maor**
Contact	Orly Maor

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