FDA 510(k) Premarket Notification

K221127 Sientra, inc. Portfinder

CLEARED

May 10, 2023
387 days to decision

K221127 · Product code: **LCJ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k221127/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tissue Expander And Accessories (LCJ)
Date received	Apr 18, 2022
Decision date	May 10, 2023
Days to decision	387 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Sientra, Inc.**
Location	Santa Barbara, CA, US
Contact	Denise Dajles
510(k) history	3 submissions · 3 cleared · 2020-2023