FDA 510(k) Premarket Notification

K243886 ExpressCore Biopsy Device

CLEARED

Apr 29, 2025
132 days to decision

K243886 · Product code: **KNW** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k243886/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Dec 18, 2024
Decision date	Apr 29, 2025
Days to decision	132 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Inrad, Inc.**
Location	Grand Rapids, MI, US
Contact	Heidi Halverson
510(k) history	4 submissions · 4 cleared · 2011-2025