FDA 510(k) Premarket Notification

CLEARED

K242175 XOD Diathermia Radiofrequency Device

Feb 27, 2025
218 days to decision

K242175 · Product code: **PBX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k242175/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Vacuum, Radio Frequency Induced Heat (PBX)
Date received	Jul 24, 2024
Decision date	Feb 27, 2025
Days to decision	218 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Xod, Inc.**
Location	Philadelphia, PA, US
Contact	Ron Gardi
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Blackwell Device Consulting**
Contact	Angela Blackwell

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