FDA 510(k) Premarket Notification

K212971 NPseal

CLEARED

Feb 10, 2022
146 days to decision

K212971 · Product code: **OKO** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k212971/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Negative Pressure Wound Therapy Non-powered Suction Apparatus (OKO)
Date received	Sep 17, 2021
Decision date	Feb 10, 2022
Days to decision	146 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Guard Medical, Inc.**
Location	New York, NY, US
Contact	Machiel Van Der Leest
510(k) history	7 submissions · 7 cleared · 2020-2025

REGULATORY CONSULTANT

Consulting firm	**AlvaMed, Inc.**
Contact	Eric Bannon

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