FDA 510(k) Premarket Notification

CLEARED

K202217 Kendall NPWT Incision Management Device

Jun 4, 2021
302 days to decision

K202217 · Product code: **OMP** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k202217/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Negative Pressure Wound Therapy Powered Suction Pump (OMP)
Date received	Aug 6, 2020
Decision date	Jun 4, 2021
Days to decision	302 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Cardinalhealth**
Location	Mcgaw Park, IL, US
Contact	Christine Kuntz-Nassif
Website	http://www.cardinalhealth.com
510(k) history	32 submissions · 32 cleared · 2003-2026

REGULATORY CONSULTANT

Consulting firm	**Patient Recovery, Cardinal Health**
Contact	Jillian Connery

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