

K143133 RENASYS₂ EZ MAX Negative Pressure Wound Therapy Device, RENASYS₂ AB Abdominal Dressing Kit with Soft Port Device

Jul 23, 2015
265 days to decision

K143133 · Product code: **OMP** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k143133/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Negative Pressure Wound Therapy Powered Suction Pump (OMP)
Date received	Oct 31, 2014
Decision date	Jul 23, 2015
Days to decision	265 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Smith & Nephew, Inc.
Location	Mchenry, IL, US
Contact	LAURA REYNOLDS
Website	http://www.smith-nephew.com/
510(k) history	530 submissions · 517 cleared · 1980-2026

Smith & Nephew, Inc. is a medical technology company focused on repair, regeneration, and replacement of soft and hard tissues. The company operates with a manufacturing facility in McHenry, US. Smith & Nephew has established a significant regulatory track record with the FDA. The company has received FDA 510(k) clearances from total submissions since 1980. Orthopedic devices represent the dominant category, accounting for 71% of submissions. The company remains active, with the latest clearance in 2025. Recent cleared devices reflect a strong focus on orthopedic surgical...