

K163387 PICO Single Use Negative Pressure Wound Therapy System

Apr 18, 2017
137 days to decisionK163387 · Product code: **OMP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k163387/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Negative Pressure Wound Therapy Powered Suction Pump (OMP)
Date received	Dec 2, 2016
Decision date	Apr 18, 2017
Days to decision	137 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Smith & Nephew Medical Limited
Location	Hull, GB
Contact	Samantha Neilson
510(k) history	20 submissions · 20 cleared · 2016-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k163387/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 1, 2026