

K133333 UNI NPWT FOAM DRESSING KIT, UNI NPWT FOAM DRESSING KIT, UNI NPWT FOAM DRESSING KIT

Dec 31, 2014
428 days to decision

K133333 · Product code: **OMP** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k133333/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Negative Pressure Wound Therapy Powered Suction Pump (OMP)
Date received	Oct 29, 2013
Decision date	Dec 31, 2014
Days to decision	428 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Blue Ocean Medical Product, LLC
Location	Crofton, MD, US
Contact	E.J. Smith
510(k) history	1 submissions · 1 cleared · 2014-2014

510k Database - www.510kdatabase.net
 Device record: <https://www.510kdatabase.net/k133333/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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