

**K142956 NewEra Small Dome Kit, NewEra Medium Dome Kit,
NewEra Large Dome Kit**Feb 24, 2015
133 days to decisionK142956 · Product code: **OMP** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k142956/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Negative Pressure Wound Therapy Powered Suction Pump (OMP)
Date received	Oct 14, 2014
Decision date	Feb 24, 2015
Days to decision	133 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Integrated Healing Technologies
Location	Franklin, TN, US
Contact	Ian Baird
510(k) history	2 submissions · 2 cleared · 2015-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k142956/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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