

**K161897 PREVENA DUO, PREVENA PLUS DUO Incision Management Systems with PEEL & PLACE Dressings**Oct 4, 2016  
85 days to decisionK161897 · Product code: **OMP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k161897/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Negative Pressure Wound Therapy Powered Suction Pump (OMP)
Date received	Jul 11, 2016
Decision date	Oct 4, 2016
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Kci USA, Inc. (Kinetic Concepts, Inc.)</b>
Location	San Antonio, TX, US
Contact	MARGARET MARSH
510(k) history	13 submissions · 13 cleared · 2006-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161897/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026