

**K122490 KULAVAC**Nov 13, 2013  
455 days to decisionK122490 · Product code: **OMP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k122490/>**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	Aug 15, 2012
Decision date	Nov 13, 2013
Days to decision	455 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>CG Bio Co., Ltd.</b>
Location	Seoul, KR
Contact	JUNGEUN IM
510(k) history	5 submissions · 5 cleared · 2013-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k122490/> 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