

K253199 CURASYS 2 (EMDN0003)Jun 23, 2026
270 days to decisionK253199 · Product code: **OMP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k253199/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Negative Pressure Wound Therapy Powered Suction Pump (OMP)
Date received	Sep 26, 2025
Decision date	Jun 23, 2026
Days to decision	270 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	CG Bio Co., Ltd.
Location	Seoul, KR
Contact	Youngwook Moon
510(k) history	6 submissions · 6 cleared · 2013-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253199/> 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 July 11, 2026