

K090612 BENACELJul 24, 2009
140 days to decisionK090612 · Product code: **OLR** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k090612/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oral Wound Dressing (OLR)
Date received	Mar 6, 2009
Decision date	Jul 24, 2009
Days to decision	140 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Unicare Biomedical
Location	Laguna Hills, CA, US
Contact	STAN YANG
510(k) history	4 submissions · 4 cleared · 1998-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k090612/> 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 June 22, 2026