

K011403 SURGIPLASTER CALCIUM SULFATE HEMIHYDRATESep 11, 2001
127 days to decisionK011403 · Product code: **LYC** · DentalSource: <https://www.510kdatabase.net/k011403/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Grafting Material, Synthetic (LYC)
Date received	May 7, 2001
Decision date	Sep 11, 2001
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Orthogen Corp.
Location	Stillwater, MN, US
Contact	ELAINE DUNCAN
510(k) history	1 submissions · 1 cleared · 2001-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k011403/> 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 2, 2026