

K102812 GAMMA-BSMDec 3, 2010
66 days to decisionK102812 · Product code: **LYC** · DentalSource: <https://www.510kdatabase.net/k102812/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Bone Grafting Material, Synthetic (LYC)
Date received	Sep 28, 2010
Decision date	Dec 3, 2010
Days to decision	66 days
Third-party review	No
Summary / Statement	Summary
Other names	BETA-BSM; EQUIVABONE

APPLICANT

Company	Etex Corporation
Location	Cambridge, MA, US
Contact	CHRISTOPHER KLACZYK
510(k) history	5 submissions · 5 cleared · 2010-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k102812/> 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 May 26, 2026