

K100883 CARRIGENDec 21, 2010
266 days to decisionK100883 · Product code: **LYC** · Dental
Source: <https://www.510kdatabase.net/k100883/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Grafting Material, Synthetic (LYC)
Date received	Mar 30, 2010
Decision date	Dec 21, 2010
Days to decision	266 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Etex Corp.
Location	Cambridge, MA, US
Contact	CHRISTOPHER KLACZYK
510(k) history	18 submissions · 17 cleared · 1994-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k100883/> 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 18, 2026