

K983009 BSM- BONE SUBSTITUTE MATERIALNov 25, 1998
89 days to decisionK983009 · Product code: **GXP** · Neurology
Source: <https://www.510kdatabase.net/k983009/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Methyl Methacrylate For Cranioplasty (GXP)
Date received	Aug 28, 1998
Decision date	Nov 25, 1998
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k983009/> 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 19, 2026