

K973706 DURA-GUARD-DURAL REPAIR PATCHDec 24, 1997
86 days to decisionK973706 · Product code: **GXQ** · Neurology
Source: <https://www.510kdatabase.net/k973706/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dura Substitute (GXQ)
Date received	Sep 29, 1997
Decision date	Dec 24, 1997
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bio-Vascular, Inc.
Location	St. Paul, MN, US
Contact	BARBARA ATZENHOEFER
510(k) history	26 submissions · 25 cleared · 1986-2000

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k973706/> 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 20, 2026