

K002334 MACROPORENS CRANILOCMay 2, 2001
274 days to decisionK002334 · Product code: **GXR** · Neurology
Source: <https://www.510kdatabase.net/k002334/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cover, Burr Hole (GXR)
Date received	Aug 1, 2000
Decision date	May 2, 2001
Days to decision	274 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Macropore Biosurgery, Inc.
Location	San Diego, CA, US
Contact	KENNITH K KLEINHENZ
510(k) history	17 submissions · 16 cleared · 2000-2004

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k002334/> 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