

K001096 BURR HOLE COVER, MODEL XXOct 25, 2000
204 days to decisionK001096 · Product code: **GXR** · Neurology
Source: <https://www.510kdatabase.net/k001096/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cover, Burr Hole (GXR)
Date received	Apr 4, 2000
Decision date	Oct 25, 2000
Days to decision	204 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Image-Guided Neurologics, Inc.
Location	Melbourne, FL, US
Contact	DAVID M LEE
510(k) history	22 submissions · 22 cleared · 1999-2005

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k001096/> 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