

K940012 SMARTBRACE ELECTRODEDec 5, 1994
335 days to decisionK940012 · Product code: **GXY** · Neurology
Source: <https://www.510kdatabase.net/k940012/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Jan 4, 1994
Decision date	Dec 5, 1994
Days to decision	335 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Medical Devices, Inc.
Location	Mchenry, IL, US
Contact	KIRBY J KUHLEMEIER
510(k) history	49 submissions · 47 cleared · 1977-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k940012/> 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 21, 2026