

K123795 AXON-BUS PROSTHETIC SYSTEMJun 3, 2014
540 days to decisionK123795 · Product code: **GXY** · Neurology
Source: <https://www.510kdatabase.net/k123795/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Dec 10, 2012
Decision date	Jun 3, 2014
Days to decision	540 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Otto Bock Austria
Location	Vienna, AT
Contact	REINHARD WOLKERSTORFER
510(k) history	1 submissions · 1 cleared · 2014-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123795/> 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 June 6, 2026