

**K080386 COLUMBIA 600 ELECTRODE, COLUMBIA 06
LEADWIRE**May 30, 2008
107 days to decisionK080386 · Product code: **GXY** · Neurology
Source: <https://www.510kdatabase.net/k080386/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Feb 13, 2008
Decision date	May 30, 2008
Days to decision	107 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Columbia Scientific Development, LLC
Location	Portland, OR, US
Contact	STEPHEN SHULMAN
510(k) history	1 submissions · 1 cleared · 2008-2008

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k080386/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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