

K182757 Espire Elbow Pro, Espire Elbow HybridNov 29, 2018
62 days to decisionK182757 · Product code: **GXY** · Neurology
Source: <https://www.510kdatabase.net/k182757/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Sep 28, 2018
Decision date	Nov 29, 2018
Days to decision	62 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	College Park Industries, Inc.
Location	Warren, MI, US
Contact	Deborah Mackmin
510(k) history	1 submissions · 1 cleared · 2018-2018

REGULATORY CONSULTANT

Consulting firm	Emergo Global Consulting, LLC
Contact	Ken Pilgrim

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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