

**K161028 K2M Growing Spine System**Jul 22, 2016  
101 days to decisionK161028 · Product code: **PGM** · Orthopedic  
Source: <https://www.510kdatabase.net/k161028/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Growing Rod System (PGM)
Date received	Apr 12, 2016
Decision date	Jul 22, 2016
Days to decision	101 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>K2m, Inc.</b>
Location	Leesburg, VA, US
Contact	Nancy Giezen
510(k) history	100 submissions · 97 cleared · 2007-2026

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