

K070012 POLYBONEDec 27, 2007
358 days to decisionK070012 · Product code: **GXP** · Neurology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Methyl Methacrylate For Cranioplasty (GXP)
Date received	Jan 3, 2007
Decision date	Dec 27, 2007
Days to decision	358 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Kyung Won Medical Co., Ltd.
Location	Santa Fe Springs, CA, US
Contact	JOO YEON LEE
510(k) history	4 submissions · 4 cleared · 2007-2010

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