

K082391 PRIMAeva MEDICAL RENESIS SYSTEMSep 1, 2009
378 days to decisionK082391 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k082391/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Aug 19, 2008
Decision date	Sep 1, 2009
Days to decision	378 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Primaeva Medical, Inc.
Location	Fremont, CA, US
Contact	BRIAN GRIGSBY
510(k) history	3 submissions · 3 cleared · 2007-2009

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