

K083721 MODIFICATION TO ZENIEVAJan 8, 2009
24 days to decisionK083721 · Product code: **NAE** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k083721/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dressing, Wound, Hydrogel Without Drug And/or Biologic (NAE)
Date received	Dec 15, 2008
Decision date	Jan 8, 2009
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	River&apos;S Edge Pharmaceuticals, LLC
Location	Durham, NC, US
Contact	SANDRA R KIRCUS
510(k) history	1 submissions · 1 cleared · 2009-2009

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