

K082865 MODIFICATION TO ZENIEVAOct 23, 2008
24 days to decisionK082865 · Product code: **NAE** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k082865/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dressing, Wound, Hydrogel Without Drug And/or Biologic (NAE)
Date received	Sep 29, 2008
Decision date	Oct 23, 2008
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gorbec Pharmaceutical Services, Inc.
Location	Durham, NC, US
Contact	SANDRA R KIRCUS
510(k) history	3 submissions · 3 cleared · 2008-2010

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