

K112191 HEALEX BIOSPONGE WOUND DRESSINGJun 5, 2012
312 days to decisionK112191 · Product code: **KGN** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k112191/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wound Dressing With Animal-derived Material(s) (KGN)
Date received	Jul 29, 2011
Decision date	Jun 5, 2012
Days to decision	312 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bionova Medical, Inc.
Location	Alexandria, VA, US
Contact	DEBORAH LAVOIE GRAYESKI
510(k) history	6 submissions · 6 cleared · 2012-2024

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