

K133011 DIAPHRAGMATIC HERNIA GRAFTJun 20, 2014
268 days to decisionK133011 · Product code: **OWV** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k133011/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Collagen, Diaphragmatic Hernia (OWV)
Date received	Sep 25, 2013
Decision date	Jun 20, 2014
Days to decision	268 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cook Biotech, Inc.
Location	West Lafayette, IN, US
Contact	MARY A FADERAN PH.D., RAC
510(k) history	31 submissions · 31 cleared · 1998-2014

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