

K131745 BLOM-SINGER SEPTAL PERFORATION PROSTHESISSep 17, 2013
96 days to decisionK131745 · Product code: **LFB** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k131745/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Button, Nasal Septal (LFB)
Date received	Jun 13, 2013
Decision date	Sep 17, 2013
Days to decision	96 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Helix Medical, LLC
Location	Carpinteria, CA, US
Contact	PAUL DRYDEN
510(k) history	4 submissions · 4 cleared · 2008-2013

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