

K130736 BLOM-SINGER ADJUSTABLE BI-FIANGED FISTULA PROSTHESISDec 17, 2013
274 days to decisionK130736 · Product code: LRC · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k130736/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Ent Manual Surgical (LRC)
Date received	Mar 18, 2013
Decision date	Dec 17, 2013
Days to decision	274 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k130736/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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