

K033398 LARYNGEAL AUGMENTATION IMPLANTDec 12, 2003
49 days to decisionK033398 · Product code: **MIX** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k033398/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Vocal Cord Medialization (MIX)
Date received	Oct 24, 2003
Decision date	Dec 12, 2003
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bioform, Inc.
Location	Franksville, WI, US
Contact	JAMES MILLER
510(k) history	4 submissions · 4 cleared · 2001-2003

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