

K974311 VOCOM (VOCAL CORD MEDIALIZATION) IMPLANTMar 4, 1998
107 days to decisionK974311 · Product code: **KHJ** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k974311/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer, Ent Synthetic-polyamide (mesh Or Foil Material) (KHJ)
Date received	Nov 17, 1997
Decision date	Mar 4, 1998
Days to decision	107 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gyrus Ent LLC
Location	Bartlett, TN, US
Contact	ALICIA FARAGE
510(k) history	28 submissions · 28 cleared · 1997-2004

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