

**K051911 GELITA-SPON**Dec 6, 2005  
145 days to decisionK051911 · Product code: **KHJ** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k051911/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer, Ent Synthetic-polyamide (mesh Or Foil Material) (KHJ)
Date received	Jul 14, 2005
Decision date	Dec 6, 2005
Days to decision	145 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Curamedical, BV</b>
Location	Claremont, NH, US
Contact	WILLIAM GREENROSE
510(k) history	2 submissions · 2 cleared · 2005-2006

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k051911/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 30, 2026