

**K121678 DTAD**Aug 30, 2012  
84 days to decisionK121678 · Product code: **ERL** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k121678/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drill, Surgical, Ent (electric Or Pneumatic) Including Handpiece (ERL)
Date received	Jun 7, 2012
Decision date	Aug 30, 2012
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gyrus Acmi, Inc.</b>
Location	Westborough, MA, US
Contact	DOLAN MILLS
Website	<a href="https://www.olympusmedical.com">https://www.olympusmedical.com</a>
510(k) history	42 submissions · 42 cleared · 2007-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k121678/> 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 13, 2026