

**K034004 DIEGO RF POWERED DISSECTOR AND DRILL  
SYSTEM CONSOLE**Mar 3, 2004  
70 days to decisionK034004 · Product code: ERL · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k034004/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drill, Surgical, Ent (electric Or Pneumatic) Including Handpiece (ERL)
Date received	Dec 24, 2003
Decision date	Mar 3, 2004
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k034004/>; 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