

**K002828 XPS NITRO SYSTEM**Oct 17, 2000  
36 days to decisionK002828 · Product code: **ERL** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k002828/>**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	Sep 11, 2000
Decision date	Oct 17, 2000
Days to decision	36 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Xomed, Inc.</b>
Location	Arnold, MO, US
Contact	MARTIN D SARGENT
510(k) history	82 submissions · 81 cleared · 1976-2000

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k002828/> 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 May 21, 2026