

**K945659 BLACKSTAR(TM) STAR SYSTEM**Jan 9, 1995  
53 days to decisionK945659 · Product code: **ERL** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k945659/>**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	Nov 17, 1994
Decision date	Jan 9, 1995
Days to decision	53 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Xomed-Treace, Inc.</b>
Location	Jacksonville, FL, US
510(k) history	12 submissions · 12 cleared · 1991-1995

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k945659/>; 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 26, 2026