

**K984035 XK-95 HIGH SPEED MOTOR DRILL SYSTEM**Jun 3, 1999  
203 days to decisionK984035 · Product code: **HBE** · Neurology  
Source: <https://www.510kdatabase.net/k984035/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drills, Burrs, Trephines & Accessories (simple, Powered) (HBE)
Date received	Nov 12, 1998
Decision date	Jun 3, 1999
Days to decision	203 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Komet Medical</b>
Location	Savannah, GA, US
Contact	COURTNEY S PARADICE
510(k) history	3 submissions · 3 cleared · 1994-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k984035/> 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