

**K944590 ETHICON DRILL BIT AND DRILL GUIDE**May 11, 1995  
234 days to decisionK944590 · Product code: **HSZ** · Orthopedic  
Source: <https://www.510kdatabase.net/k944590/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Surgical, Orthopedic, Pneumatic Powered & Accessory/attachment (HSZ)
Date received	Sep 19, 1994
Decision date	May 11, 1995
Days to decision	234 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Ethicon, Inc.</b>
Location	Raritan, NJ, US
Contact	JOHN D PAULSON
Website	<a href="https://www.jnjmedtech.com">https://www.jnjmedtech.com</a>
510(k) history	203 submissions · 196 cleared · 1976-2026

Ethicon, Inc. is a subsidiary of Johnson & Johnson specializing in surgical sutures and wound closure devices. The company is headquartered in Raritan, United States. Ethicon has received FDA 510(k) clearances from total submissions since 1976. The company's regulatory focus centers on General & Plastic Surgery devices, which represent the majority of its cleared submissions. The latest FDA 510(k) clearance was granted in 2026, demonstrating continued regulatory activity. Ethicon has manufactured surgical sutures and wound closure technologies since 1887. The company hold...

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