

**K961467 HEAD RETAINING DEVICE**Aug 9, 1996  
116 days to decisionK961467 · Product code: **IYE** · Radiology  
Source: <https://www.510kdatabase.net/k961467/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Apr 15, 1996
Decision date	Aug 9, 1996
Days to decision	116 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>S. and H. Engineering, Inc.</b>
Location	Miami, FL, US
Contact	SYDNEY GOLDSTEIN
510(k) history	4 submissions · 4 cleared · 1992-1996

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k961467/> 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 20, 2026