

**K972617 HELAX-VISIR**Oct 1, 1997  
84 days to decisionK972617 · Product code: **IYE** · Radiology  
Source: <https://www.510kdatabase.net/k972617/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Jul 9, 1997
Decision date	Oct 1, 1997
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Helax AB</b>
Location	Uppsala, SE
Contact	JAN TORNQVIST
510(k) history	3 submissions · 3 cleared · 1997-1999

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