

**K080359 EVOLUTION ESOPHAGEAL STENT SYSTEM**May 9, 2008  
88 days to decisionK080359 · Product code: **ESW** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k080359/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Esophageal (ESW)
Date received	Feb 11, 2008
Decision date	May 9, 2008
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cook Ireland, Ltd.</b>
Location	Limerick, IE
Contact	NOREEN BARRY
510(k) history	32 submissions · 27 cleared · 2005-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k080359/> 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 14, 2026