

**K093619 EVOLUTION ESOPHAGEAL STENT FULLY COVERED,
MODELS EVO-FC-18-23-8-E, EVO-FC-18-23-10-E, EVO-
FC-18-23-12-E**Jun 17, 2010
206 days to decisionK093619 · Product code: **ESW** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k093619/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Esophageal (ESW)
Date received	Nov 23, 2009
Decision date	Jun 17, 2010
Days to decision	206 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cook Ireland, Ltd.
Location	Limerick, IE
Contact	Jacinta Kilmartin
510(k) history	32 submissions · 27 cleared · 2005-2024

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