FDA 510(k) Premarket Notification

K101530 EVOLUTION DUODENAL STENT SYSTEM, MODEL EVO-22-27-6-D, EVO-22-27-9-D, EVP-22-27-12-D

CLEARED

Mar 29, 2011
299 days to decision

K101530 · Product code: **MUM** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k101530/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stent, Metallic, Expandable, Duodenal (MUM)
Date received	Jun 3, 2010
Decision date	Mar 29, 2011
Days to decision	299 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