

K172044 Cotton-Huibregtse Stent, Cotton-Leung Biliary Stent, Cotton-Leung Sof-Flex Biliary Stent, Soehendra Tannenbaum Biliary Stent, Zimmon Biliary Stent, Guiding Catheter, Pushing catheter, Fusion pushing catheter, Stent Introducer Set, Fusion Oasis One Action Sent Introduction System, Zimmon Biliary Stent Set, Oasis One Action Stent Introduction System, Solus Double Pigtail Stent and Introduction System, Cotton-Huibregtse Biliary Stent Set, Cotton-Leung Biliary Stent Set, Oasis One Action S

Feb 27, 2018
236 days to decision

K172044 · Product code: FGE · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k172044/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Jul 6, 2017
Decision date	Feb 27, 2018
Days to decision	236 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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