

K844384 BILIARY STENT PROSTHESISFeb 14, 1985
93 days to decisionK844384 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k844384/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Nov 13, 1984
Decision date	Feb 14, 1985
Days to decision	93 days
Third-party review	No

APPLICANT

Company	Mentor Corp.
Location	Mchenry, IL, US
Contact	CHRISTINE EMANUEL
510(k) history	61 submissions · 61 cleared · 1977-2013

Mentor Corp. is a surgical aesthetics and medical device company based in McHenry, US. Now part of Johnson & Johnson MedTech, the brand supplies products to plastic surgeons and specialists worldwide. Mentor has received FDA 510(k) clearances from total submissions since its first clearance in 1977. The company's regulatory record spans General & Plastic Surgery, Gastroenterology & Urology, Obstetrics & Gynecology, and Radiology device categories. The latest clearance was recorded in 2013, reflecting the company's historical significance in surgical device innovation. Men...
