

**K911581 PALMAZ(TM) BALLOON-EXPANDABLE STENT,
MODIFICATION**Jun 4, 1991
56 days to decisionK911581 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k911581/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Apr 9, 1991
Decision date	Jun 4, 1991
Days to decision	56 days
Third-party review	No

APPLICANT

Company	Johnson & Johnson Interventional Systems
Location	Warren, NJ, US
Contact	JAMES P O'CONNOR;DONNELL
510(k) history	2 submissions · 2 cleared · 1991-1991

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k911581/> Data sourced from FDA 510(k) public records (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. - Generated July 2, 2026