

K880343 BURNEY GALLBLADDER CATHETER KITMay 1, 1989
461 days to decisionK880343 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k880343/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Jan 26, 1988
Decision date	May 1, 1989
Days to decision	461 days
Third-party review	No

APPLICANT

Company	Mallinckrodt Critical Care
Location	Mchenry, IL, US
Contact	ROBERT S LAKE
Website	https://www.mallinckrodt.com
510(k) history	92 submissions · 92 cleared · 1976-1989

Mallinckrodt Critical Care is a medical device manufacturer based in McHenry, US. Now part of Mallinckrodt plc following a 2025 merger and subsequent restructuring, the company maintains a significant historical regulatory record in critical care and specialty medical devices. The company received FDA 510(k) clearances from total submissions between 1976 and 1989. Device clearances span anesthesiology, cardiovascular, gastroenterology, and general hospital categories. Notable cleared products include tracheal tubes, temperature monitoring systems, catheters, and related c...

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k880343/> 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 May 21, 2026