

K770706 CATHETER, IRRIGATIONMay 6, 1977
18 days to decisionK770706 · Product code: **GBX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k770706/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Irrigation (GBX) |
| Date received | Apr 18, 1977 |
| Decision date | May 6, 1977 |
| Days to decision | 18 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Mallinckrodt Critical Care |
| Location | Mchenry, IL, US |
| 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...
