

K821180 TRACELONMay 21, 1982
24 days to decisionK821180 · Product code: **BTR** · AnesthesiologySource: <https://www.510kdatabase.net/k821180/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube, Tracheal (w/wo Connector) (BTR)
Date received	Apr 27, 1982
Decision date	May 21, 1982
Days to decision	24 days
Third-party review	No

APPLICANT

Company	Terumo Medical Corp.
Location	Elkton, MD, US
510(k) history	143 submissions · 143 cleared · 1980-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k821180/> 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 27, 2026