

K925615 SHILEY SPECIALIZED,PEDIATRIC & NEONATAL TRACH.TUBE

Mar 26, 1993
140 days to decision

K925615 · Product code: **CBI** · Anesthesiology
Source: <https://www.510kdatabase.net/k925615/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube, Tracheal/bronchial, Differential Ventilation (w/wo Connector) (CBI)
Date received	Nov 6, 1992
Decision date	Mar 26, 1993
Days to decision	140 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Sorin Biomedica, Fiat, USA, Inc.
Location	Mchenry, IL, US
Contact	AMY BOUCLY
510(k) history	20 submissions · 20 cleared · 1980-1994

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k925615/> 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 26, 2026