

**K000001 WALLGRAFT TRACHEOBRONCHIAL
ENDOPROSTHESIS AND UNISTEP DELIVERY SYSTEM**Jun 5, 2000
154 days to decision

K000001 · Product code: JCT · General & Plastic Surgery

Source: <https://www.510kdatabase.net/k000001/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Tracheal, Expandable (JCT)
Date received	Jan 3, 2000
Decision date	Jun 5, 2000
Days to decision	154 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific Scimed, Inc.
Location	Plymouth, MN, US
Contact	RON BENNETT
510(k) history	35 submissions · 26 cleared · 1994-2004

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k000001/> 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 June 28, 2026