FDA 510(k) Premarket Notification

K980113 WALLSTENT ENTERAL ENDOPROSTHESIS

CLEARED

Apr 3, 1998
80 days to decision

K980113 · Product code: **MUM** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k980113/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stent, Metallic, Expandable, Duodenal (MUM)
Date received	Jan 13, 1998
Decision date	Apr 3, 1998
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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