

K013866 CONVOY ADVANCED DELIVERY SHEATH KITDec 14, 2001
23 days to decisionK013866 · Product code: **DBY** · Immunology
Source: <https://www.510kdatabase.net/k013866/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fab, Rhodamine, Antigen, Antiserum, Control (DBY)
Date received	Nov 21, 2001
Decision date	Dec 14, 2001
Days to decision	23 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific
Location	San Jose, CA, US
Contact	ANDREA L RUTH
Website	http://www.bostonscientific.com/
510(k) history	58 submissions · 52 cleared · 2001-2026

Boston Scientific is an American biotechnology and biomedical engineering firm headquartered in Marlborough, Massachusetts. The company manufactures medical devices for interventional specialties including cardiology, endoscopy, urology, and oncology. Boston Scientific has received FDA 510(k) clearances from total submissions since 2001. The company maintains active regulatory engagement, with the latest clearance in 2025. Recent cleared devices span cardiovascular, gastroenterology, urology, orthopedic, and general surgery categories, reflecting broad therapeutic focus. ...
