

K110971 TRACER IMPLANTATION KIT, INDEX IMPLANTATION KITJan 10, 2012
279 days to decisionK110971 · Product code: **IYE** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k110971/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Apr 6, 2011
Decision date	Jan 10, 2012
Days to decision	279 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Navotek Medical, Ltd.
Location	Philedelphia, PA, US
Contact	STEVEN B DATLOF
510(k) history	2 submissions · 2 cleared · 2011-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k110971/> 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 17, 2026