

K141634 NAUTILUS DELTAJan 27, 2015
223 days to decisionK141634 · Product code: **LJS** · General Hospital
Source: <https://www.510kdatabase.net/k141634/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Catheter, Intravascular, Therapeutic, Long-term Greater Than 30 Days (LJS)
Date received	Jun 18, 2014
Decision date	Jan 27, 2015
Days to decision	223 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Romedex International Srl
Location	Palo Alto, CA, US
Contact	SORIN GRUNWALD
510(k) history	2 submissions · 2 cleared · 2010-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k141634/> 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 5, 2026