

**K050916 SAFE-CROSS RADIO FREQUENCY TOTAL
OCCLUSION CROSSING SYSTEM [PERIPHERAL]**Jun 8, 2005
57 days to decisionK050916 · Product code: **PDU** · Cardiovascular
Source: <https://www.510kdatabase.net/k050916/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter For Crossing Total Occlusions (PDU)
Date received	Apr 12, 2005
Decision date	Jun 8, 2005
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Intra Luminal Therapeutics, Inc.
Location	Carlsbad, CA, US
Contact	PAMELA MISAJON
510(k) history	20 submissions · 20 cleared · 2000-2005

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k050916/> 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 July 2, 2026