FDA 510(k) Premarket Notification

K033929 MODIFICATION TO SAFE-CROSS RADIO FREQUENCY TOTAL OCCLUSION CROSSING SYSTEM

CLEARED

Jan 12, 2004
25 days to decision

K033929 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k033929/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wire, Guide, Catheter (DQX)
Date received	Dec 18, 2003
Decision date	Jan 12, 2004
Days to decision	25 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