FDA 510(k) Premarket Notification

K040037 MODIFICATION TO SAFE-CROSS RADIO FREQUENCY TOTAL OCCLUSION CROSSING SYSTEM

CLEARED

Mar 3, 2004
54 days to decision

K040037 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k040037/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wire, Guide, Catheter (DQX)
Date received	Jan 9, 2004
Decision date	Mar 3, 2004
Days to decision	54 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