FDA 510(k) Premarket Notification

K033708 MODIFICATION TO SAFE-CROSS RADIO FREQUENCY TOTAL OCCLUSION CROSSING SYSTEM

CLEARED

Dec 11, 2003
15 days to decision

K033708 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k033708/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wire, Guide, Catheter (DQX)
Date received	Nov 26, 2003
Decision date	Dec 11, 2003
Days to decision	15 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