FDA 510(k) Premarket Notification

K031842 SAFE-CROSS RADIO FREQUENCY TOTAL OCCLUSION CROSSING SYSTEM

CLEARED

Nov 21, 2003
158 days to decision

K031842 · Product code: **PDU** · Cardiovascular
Source: https://www.510kdatabase.net/k031842/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter For Crossing Total Occlusions (PDU)
Date received	Jun 16, 2003
Decision date	Nov 21, 2003
Days to decision	158 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