FDA 510(k) Premarket Notification

K032031 SAFE-CROSS RADIO FREQUENCY TOTAL OCCLUSION CROSSING SYSTEM

CLEARED

Jan 7, 2004
190 days to decision

K032031 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k032031/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Jul 1, 2003
Decision date	Jan 7, 2004
Days to decision	190 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