FDA 510(k) Premarket Notification

K992622 INTRAMAX ITI GUIDE CATHETER

CLEARED

Sep 29, 1999
55 days to decision

K992622 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k992622/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Aug 5, 1999
Decision date	Sep 29, 1999
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Intratherapeutics, Inc.**
Location	Saint Paul, MN, US
Contact	AMY PETERSON
510(k) history	15 submissions · 7 cleared · 1998-2001