FDA 510(k) Premarket Notification

K001424 KAWASUMI LABORATORIES IV ADMINISTRATION SET, STANDARD

CLEARED

Jul 21, 2000
77 days to decision

K001424 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k001424/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	May 5, 2000
Decision date	Jul 21, 2000
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Kawasumi Laboratories America, Inc.**
Location	Tampa, FL, US
Contact	JACK PAVLO
510(k) history	6 submissions · 6 cleared · 2000-2010