FDA 510(k) Premarket Notification

K921902 PORT ACCESS NEEDLE

CLEARED

Jul 28, 1993
462 days to decision

K921902 · Product code: **LJT** · General Hospital
Source: https://www.510kdatabase.net/k921902/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Port & Catheter, Implanted, Subcutaneous, Intravascular (LJT)
Date received	Apr 22, 1992
Decision date	Jul 28, 1993
Days to decision	462 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Kawasumi Laboratories Co., Ltd.**
Location	Canoga Park, CA, US
Contact	SHOZO MORIYAMA
510(k) history	18 submissions · 18 cleared · 1987-2000