FDA 510(k) Premarket Notification

K991027 BI-DIRECTIONAL TUNNELER

CLEARED

Apr 22, 1999
24 days to decision

K991027 · Product code: **DSY** · Cardiovascular
Source: https://www.510kdatabase.net/k991027/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Vascular Graft, Of 6mm And Greater Diameter (DSY)
Date received	Mar 29, 1999
Decision date	Apr 22, 1999
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Impra, Inc.**
Location	Mchenry, IL, US
Contact	KRISTI M KISTNER
510(k) history	29 submissions · 24 cleared · 1979-2001