FDA 510(k) Premarket Notification

K925395 TECHNOMED PULSOLITH 4000 LASER SYSTEM

CLEARED

May 21, 1993
207 days to decision

K925395 · Product code: **LNK** · General Hospital
Source: https://www.510kdatabase.net/k925395/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser For Gastro-urology Use (LNK)
Date received	Oct 26, 1992
Decision date	May 21, 1993
Days to decision	207 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Teknomed, Inc.**
Location	Mchenry, IL, US
Contact	JEAN-LUC BOULNOIS
510(k) history	7 submissions · 7 cleared · 1979-1993