FDA 510(k) Premarket Notification

K930218 SUBCUTANEOUS TUNNELING NEEDLE AND HANDLES

CLEARED

Jul 27, 1993
193 days to decision

K930218 · Product code: **MAJ** · General Hospital
Source: https://www.510kdatabase.net/k930218/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous, Intraspinal, Short Term (MAJ)
Date received	Jan 15, 1993
Decision date	Jul 27, 1993
Days to decision	193 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Concord/Portex**
Location	Keene, NH, US
Contact	TIMOTHY J TALCOTT
510(k) history	23 submissions · 20 cleared · 1989-1993

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k930218/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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