FDA 510(k) Premarket Notification

K972158 GO MEDICAL PATIENT CONTROLLED ANALGESIA DEVICES

CLEARED

Feb 20, 1998
256 days to decision

K972158 · Product code: **MEB** · General Hospital
Source: https://www.510kdatabase.net/k972158/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion, Elastomeric (MEB)
Date received	Jun 9, 1997
Decision date	Feb 20, 1998
Days to decision	256 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Princeton Regulatory Assoc.**
Location	Princeton, NJ, US
Contact	THOMAS BECZE
510(k) history	4 submissions · 4 cleared · 1996-1998

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k972158/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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