FDA 510(k) Premarket Notification

K020421 GO MEDICAL PATIENT CONTROLLED ANALGESIA DEVICES

CLEARED

Apr 29, 2003
446 days to decision

K020421 · Product code: **MEA** · General Hospital
Source: https://www.510kdatabase.net/k020421/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion, Pca (MEA)
Date received	Feb 7, 2002
Decision date	Apr 29, 2003
Days to decision	446 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Hennig Enterprises Europe Srl**
Location	Perth, AU
Contact	GEORGE O'NEIL
510(k) history	2 submissions · 2 cleared · 2003-2003