FDA 510(k) Premarket Notification

K041280 HUMAN SUBCUTANEOUS INJECTOR, MODEL HSI 500

CLEARED

Jun 24, 2004
42 days to decision

K041280 · Product code: **KZE** · General Hospital
Source: https://www.510kdatabase.net/k041280/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Injector, Fluid, Non-electrically Powered (KZE)
Date received	May 13, 2004
Decision date	Jun 24, 2004
Days to decision	42 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Felton International, Inc.**
Location	Lenexa, KS, US
Contact	JIM STANLEY
510(k) history	2 submissions · 2 cleared · 2001-2004