FDA 510(k) Premarket Notification

K041665 L1-PRO SYSTEM

CLEARED

Jul 23, 2004
35 days to decision

K041665 · Product code: **FMK** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k041665/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single Use Only Blood Lancet With An Integral Sharps Injury Prevention Feature (FMK)
Date received	Jun 18, 2004
Decision date	Jul 23, 2004
Days to decision	35 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Pelikan Technologies, Inc.**
Location	Palo Alto, CA, US
Contact	JACK S GREEN
510(k) history	2 submissions · 2 cleared · 2003-2004