FDA 510(k) Premarket Notification

K020189 EXEL BUTTERFLY SCALP VEIN SET

CLEARED

Mar 27, 2003
433 days to decision

K020189 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k020189/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Jan 18, 2002
Decision date	Mar 27, 2003
Days to decision	433 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Exelint International, Co.**
Location	Los Angeles, CA, US
Contact	TAMMIE EWING
510(k) history	7 submissions · 7 cleared · 2000-2025