FDA 510(k) Premarket Notification

K063151 HUMAPEN LUXURA HD

CLEARED

Jan 9, 2007
85 days to decision

K063151 · Product code: **NSC** · General Hospital
Source: https://www.510kdatabase.net/k063151/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector, Pen (NSC)
Date received	Oct 16, 2006
Decision date	Jan 9, 2007
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Eli Lilly and Co.**
Location	Indianapolis, IN, US
Contact	LEEANN CHAMBERS
510(k) history	2 submissions · 2 cleared · 1998-2007