FDA 510(k) Premarket Notification

K100988 HUMAPEN LUXURA HD

CLEARED

Aug 17, 2010
130 days to decision

K100988 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k100988/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Apr 9, 2010
Decision date	Aug 17, 2010
Days to decision	130 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Eli Lilly and Company**
Location	Indianapolis, IN, US
Contact	STEVEN T JOHNSON PE, MBA
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510(k) history	5 submissions · 5 cleared · 2006-2022