FDA 510(k) Premarket Notification

K123710 UNITOX BOTOX SYRINGE

CLEARED

May 9, 2013
156 days to decision

K123710 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k123710/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Dec 4, 2012
Decision date	May 9, 2013
Days to decision	156 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bio-Med USA, Inc.**
Location	Paterson, NJ, US
Contact	YOUNG CHI
510(k) history	10 submissions · 10 cleared · 2008-2022