FDA 510(k) Premarket Notification

K093524 PIVIT A/B ST AND PIVIT A/B ST-R

CLEARED

Mar 26, 2010
130 days to decision

K093524 · Product code: **FTL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k093524/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Nov 16, 2009
Decision date	Mar 26, 2010
Days to decision	130 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Tyrx, Inc.**
Location	Monmouth Junction, NJ, US
Contact	MARK CITRON
510(k) history	5 submissions · 5 cleared · 2010-2015