FDA 510(k) Premarket Notification

K131007 AIGIS RX N MEDIUM

CLEARED

Jul 10, 2013
90 days to decision

K131007 · Product code: **FTL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k131007/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Apr 11, 2013
Decision date	Jul 10, 2013
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary
Other names	AIGIS RX N LARGE

APPLICANT

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