FDA 510(k) Premarket Notification

K150906 ULTRAPRO ADVANCED Macroporous Partically Absorbable Mesh

CLEARED

Jul 24, 2015
112 days to decision

K150906 · Product code: **FTL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k150906/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Apr 3, 2015
Decision date	Jul 24, 2015
Days to decision	112 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ehicon, Inc.**
Location	Somerville, NJ, US
Contact	SUSAN LIN
510(k) history	1 submissions · 1 cleared · 2015-2015