FDA 510(k) Premarket Notification

K170134 Reperen Surgical Mesh

CLEARED

Aug 9, 2017
204 days to decision

K170134 · Product code: **FTL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k170134/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Jan 17, 2017
Decision date	Aug 9, 2017
Days to decision	204 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Iconlab, Inc.**
Location	Aliso Viejo, CA, US
Contact	Pavel Paul Artemow
510(k) history	1 submissions · 1 cleared · 2017-2017