FDA 510(k) Premarket Notification

K092538 REFINE SUPPORT SYSTEM, MODEL 100.0100

CLEARED

Mar 5, 2010
198 days to decision

K092538 · Product code: **FTL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k092538/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Aug 19, 2009
Decision date	Mar 5, 2010
Days to decision	198 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Alure Medical, Inc.**
Location	Carlsbad, CA, US
Contact	JOSEPH TAMAYO
510(k) history	2 submissions · 2 cleared · 2009-2010