FDA 510(k) Premarket Notification

K031188 ORTHOMEND

CLEARED

Jun 27, 2003
73 days to decision

K031188 · Product code: **FTL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k031188/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Apr 15, 2003
Decision date	Jun 27, 2003
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Tei Biosciences, Inc.**
Location	Boston, MA, US
Contact	KENNETH JAMES
510(k) history	16 submissions · 16 cleared · 2002-2017