FDA 510(k) Premarket Notification

K031225 TIMESH ALSO KNOWN AS TIMESH-TC, MODELS 6000001 & 6000004

CLEARED

Sep 29, 2003
165 days to decision

K031225 · Product code: **FTL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k031225/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Apr 17, 2003
Decision date	Sep 29, 2003
Days to decision	165 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Gfe Medizintechnik GmbH**
Location	Salt Lake City, UT, US
Contact	JOHN E SAWYER
510(k) history	1 submissions · 1 cleared · 2003-2003