FDA 510(k) Premarket Notification

K102788 TORNIER BIOFIBER SCAFFOLD

CLEARED

May 10, 2011
228 days to decision

K102788 · Product code: **FTL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k102788/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Sep 24, 2010
Decision date	May 10, 2011
Days to decision	228 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Tornier, Inc.**
Location	Beverly, MA, US
Contact	LAEL J PICKETT
510(k) history	51 submissions · 51 cleared · 2000-2026