

K102788 TORNIER BIOFIBER SCAFFOLDMay 10, 2011
228 days to decisionK102788 · Product code: **FTL** · General & Plastic SurgerySource: <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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k102788/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 19, 2026