FDA 510(k) Premarket Notification

K081348 TENODESIS CROSS SCREW, INTERFERENCE SCREW, SUTURE BEAD

CLEARED

Oct 17, 2008
156 days to decision

K081348 · Product code: **MBI** · Orthopedic
Source: https://www.510kdatabase.net/k081348/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	May 14, 2008
Decision date	Oct 17, 2008
Days to decision	156 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**TriMed, Inc.**
Location	Saugus, CA, US
Contact	KELLI ANDERSON
510(k) history	35 submissions · 35 cleared · 2005-2026