FDA 510(k) Premarket Notification

K123409 QUILL MONODERM KNOTLESS TISSUE-CLOSURE DEVICE, VARIABLE LOOP DESIGN

CLEARED

Nov 20, 2012
15 days to decision

K123409 · Product code: **GAM** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k123409/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Absorbable, Synthetic, Polyglycolic Acid (GAM)
Date received	Nov 5, 2012
Decision date	Nov 20, 2012
Days to decision	15 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Surgical Specialties Corp. Dba Angiotech**
Location	Reading, PA, US
Contact	KIRSTEN STOWELL
510(k) history	7 submissions · 7 cleared · 2012-2013