FDA 510(k) Premarket Notification

K122048 COLLAGEN TENDON SHEET-D

CLEARED

Jan 8, 2013
180 days to decision

K122048 · Product code: **FTM** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k122048/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical (FTM)
Date received	Jul 12, 2012
Decision date	Jan 8, 2013
Days to decision	180 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Rotation Medical, Inc.**
Location	Plymouth, MN, US
Contact	JEFF SIMS
510(k) history	5 submissions · 5 cleared · 2011-2014