

K140300 COLLAGEN TENDON SHEET-DDI (CTS-DDI)Mar 26, 2014
48 days to decisionK140300 · Product code: **OWY** · Orthopedic
Source: <https://www.510kdatabase.net/k140300/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Collagen, Orthopaedics, Reinforcement Of Tendon (OWY)
Date received	Feb 6, 2014
Decision date	Mar 26, 2014
Days to decision	48 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

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