FDA 510(k) Premarket Notification

K173579 Thorecon™ Fixation System

CLEARED

Feb 12, 2018
84 days to decision

K173579 · Product code: **JDQ** · Orthopedic
Source: https://www.510kdatabase.net/k173579/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cerclage, Fixation (JDQ)
Date received	Nov 20, 2017
Decision date	Feb 12, 2018
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**A & E Medical Corporation**
Location	Farmingdale, NJ, US
Contact	Dana Rodriguez
510(k) history	4 submissions · 4 cleared · 2018-2020

REGULATORY CONSULTANT

Consulting firm	**Rti Surgical, Inc.**
Contact	Sarah Pleaugh

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov