

K191287 OptiFix AT Absorbable Fixation System with Articulating Technology – 30 Fasteners, OptiFix AT Absorbable Fixation System with Articulating Technology – 15 Fasteners

Jul 16, 2019
64 days to decision

K191287 · Product code: **GDW** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k191287/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Staple, Implantable (GDW)
Date received	May 13, 2019
Decision date	Jul 16, 2019
Days to decision	64 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Davol Inc., Subsidiary of C.R. Bard
Location	Warwick, RI, US
Contact	Angelica Hutchison
510(k) history	1 submissions · 1 cleared · 2019-2019

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k191287/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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