

K192566 Reach and CQ'ENCE Circular StaplersOct 17, 2019
29 days to decisionK192566 · Product code: **GDW** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k192566/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Staple, Implantable (GDW)
Date received	Sep 18, 2019
Decision date	Oct 17, 2019
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Reach Surgical, Inc.
Location	Cincinnati, OH, US
Contact	Mark Goldin
510(k) history	3 submissions · 3 cleared · 2008-2019

REGULATORY CONSULTANT

Consulting firm	Secqure Surgical
Contact	Rich Grant

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192566/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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