

K210278 Titan SGSApr 28, 2021
86 days to decisionK210278 · Product code: **GDW** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k210278/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Staple, Implantable (GDW)
Date received	Feb 1, 2021
Decision date	Apr 28, 2021
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Standard Bariatrics
Location	Cincinnati, OH, US
Contact	Alison Sathe
510(k) history	10 submissions · 10 cleared · 2016-2021

CLINICAL EVIDENCE - NCT04086433

Gastric Tissue Stapler Comparison Study

Status	Completed
Enrollment	36 patients (actual)
Study sites	1 site
Condition studied	Gastric Resection
Study type	Observational
Completion date	Oct 30, 2019
Sponsor	Standard Bariatrics (Industry)

Primary outcome**Pressure Evaluation**Source: [ClinicalTrials.gov](https://clinicaltrials.gov) / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04086433

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210278/> Data sourced from FDA 510(k) public records (accessdata.fda.gov), [ClinicalTrials.gov](https://clinicaltrials.gov) (U.S. National Library of Medicine).
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