

K243359 MagDI System (MAG-02, DS-01)Feb 28, 2025
122 days to decisionK243359 · Product code: **SAH** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k243359/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Magnetic Compression Anastomosis System (SAH)
Date received	Oct 29, 2024
Decision date	Feb 28, 2025
Days to decision	122 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Gt Metabolic Solutions, Inc.
Location	San Jose, CA, US
Contact	Lisa Griffin Vincent
510(k) history	3 submissions · 2 cleared · 2024-2025

CLINICAL EVIDENCE - NCT06467955**MagDI Canada Study**

Status	Recruiting - <i>No results published to ClinicalTrials.gov</i>
Enrollment	60 patients (estimated)
Study sites	3 sites
Condition studied	Obesity; Type 2 Diabetes
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Dec 1, 2026
Sponsor	GT Metabolic Solutions, Inc. (Industry)

Primary outcome

Performance of the side-to-side anastomosis for duodeno-ileal diversion using the MagDI System.

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT06467955510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243359/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov), ClinicalTrials.gov (U.S. National Library of Medicine).
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