FDA 510(k) Premarket Notification

K253657 Tri-staple 2.0™ Reloads

CLEARED

Apr 10, 2026
141 days to decision

K253657 · Product code: **GDW** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k253657/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Staple, Implantable (GDW)
Date received	Nov 20, 2025
Decision date	Apr 10, 2026
Days to decision	141 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Endo GIA™ Reloads with Tri-Staple™ Technology; Endo GIA™ Gray Articulating Reloads; Signia™ Small Diameter Reloads

APPLICANT

Company	**Covidien (Part of Medtronic)**
Location	North Haven, CT, US
Contact	Fei Li
510(k) history	2 submissions · 2 cleared · 2024-2026

CLINICAL EVIDENCE - NCT05095935

Medtronic Signia SDR Product Surveillance Registry

Status	Completed
Enrollment	430 patients (actual)
Study sites	14 sites
Condition studied	Minimally Invasive Surgical Procedures; Surgical Procedures, Operative
Study type	Observational
Completion date	Oct 1, 2024
Sponsor	Medtronic (Industry)

Primary outcome

Incidence of Intraoperative Hemostatic Intervention

Secondary outcome

Incidence of Repeat Hospital Admission for Primary Procedure-related Complications

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05095935