

K253527 Tri-Staple™ 2.0 Black Circular Reload 21mm Extra Thick (SIGCIR21XT)

Jul 1, 2026
230 days to decision

K253527 · Product code: **GAG** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k253527/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stapler, Surgical (GAG)
Date received	Nov 13, 2025
Decision date	Jul 1, 2026
Days to decision	230 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary
Other names	Tri-Staple™ 2.0 Black Circular Reload 25mm Extra Thick (SIGCIR25XT)

APPLICANT

Company	Covidien, LLC
Location	Mansfield, MA, US
Contact	Frank Maistrovich
510(k) history	90 submissions · 87 cleared · 2010-2026