

K253858 GFS - Sterile Screws and Top Hat

Aug 5, 2026
245 days to decision

K253858 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k253858/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Screw, Fixation, Bone (HWC)
Date received	Dec 3, 2025
Decision date	Aug 5, 2026
Days to decision	245 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	T.A.G. Medical Products Corporation, Ltd.
Location	Somerset, MA, US
Contact	Shlomi Dines
510(k) history	12 submissions · 12 cleared · 2011-2026