

K223500 SuperBall Meniscal Repair SystemAug 10, 2023
262 days to decisionK223500 · Product code: **GAT** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k223500/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Nonabsorbable, Synthetic, Polyethylene (GAT)
Date received	Nov 21, 2022
Decision date	Aug 10, 2023
Days to decision	262 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Arcuro Medical , Ltd.
Location	Misgav, IL
Contact	Lee Ranon
510(k) history	3 submissions · 3 cleared · 2018-2025

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	Janice M. Hogan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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