FDA 510(k) Premarket Notification

K211178 DURAMESH Mesh Suture

CLEARED

Sep 2, 2022
500 days to decision

K211178 · Product code: **GAW** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k211178/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Nonabsorbable, Synthetic, Polypropylene (GAW)
Date received	Apr 20, 2021
Decision date	Sep 2, 2022
Days to decision	500 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Msi**
Location	Chicago, IL, US
Contact	Greg Dumanian
510(k) history	1 submissions · 1 cleared · 2022-2022

CLINICAL EVIDENCE - NCT03940560

Mesh Suture for Internal Load Bearing Closures

Status	Withdrawn - *No results published to ClinicalTrials.gov*
Study sites	1 site
Condition studied	Suture; Complications, Mechanical; Suture; Complications, Infection or Inflammation; Suture, Complication
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Dec 31, 2025
Sponsor	Wigmore Clinic (Other)

Primary outcome

Surgery healing complication, acute

Secondary outcome

Surgery healing complication, delayed

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03940560