

K251700 Ganymede 2cm diameter (FG100300)Feb 26, 2026
269 days to decisionK251700 · Product code: **QSY** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k251700/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemostatic Wound Dressing Without Thrombin Or Other Biologics (QSY)
Date received	Jun 2, 2025
Decision date	Feb 26, 2026
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Ganymede 5cm x 5cm (FG100400); Ganymede 10cm x 10cm (FG100500); Ganymede 15cm x 15cm (FG100600); Ganymede 20cm x 30cm (FG100700); Ganymede 25cm x 25cm (FG100800); Ganymede 30cm x 30cm (FG100900); Ganymede 40cm x 40cm (FG100999); Ganymede 7.5cm x 120cm (FG100100); Ganymede-X 2cm diameter (FG100301); Ganymede-X 5cm x 5cm (FG100401); Ganymede-X 10cm x 10cm (FG100501); Ganymede-X 15cm x 15cm (FG100601); Ganymede-X 20cm x 30cm (FG100701); Ganymede-X 25cm

APPLICANT

Company	Speciality Fibres and Materials Limited
Location	Coventry, GB
Contact	Graeme Kettlewell
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	Compliance Solutions, Inc.
Contact	Angela Paterson

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

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