February 26, 2026

Speciality Fibres and Materials Limited
℅ Angela Paterson
Principal Consultant
Compliance Solutions Inc
10124 NW 53rd Street
Sunrise, Florida 33351

Re: K251700
Trade/Device Name: Ganymede and Ganymede-X
Regulatory Class: Unclassified
Product Code: QSY
Dated: January 28, 2026
Received: January 28, 2026

Dear Angela Paterson:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Yu-chieh Chiu -S

Yu-Chieh Chiu, Ph.D.
Assistant Director
DHT4B: Division of Plastic and
Reconstructive Surgery Devices
OHT4: Office of Surgical and
Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251700

Device Name
Ganymede and Ganymede-X

Indications for Use *(Describe)*
Over the counter:
Ganymede and Ganymede-X are intended for temporary external use to stop bleeding of superficial wounds, minor cuts, and abrasions.

Prescription Use:
Ganymede and Ganymede-X are intended to be used as a hemostatic dressing for local temporary management of moderately to severely bleeding wounds such as surgical wounds (operative, postoperative, dermatological), including junctional wounds not amenable to tourniquet use and traumatic injuries

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Speciality Fibres and Materials Ltd.

Traditional 510(k)

For Ganymede and Ganymede-X

510K Summary

This 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92.

Submitter:

Speciality Fibres and Materials Ltd.

Submitter's Address:

Galaxy House
31 Herald Way
Binley Industrial Estate
Coventry
CV3 2RQ
United Kingdom

Establishment Registration Number:

3005818605

Contact Person:

Angela Paterson

Date prepared:

28th January 2026

Speciality Fibres and Materials Ltd.

Traditional 510(k)

For Ganymede and Ganymede-X

Below summarizes the Device Classification Information regarding the Ganymede and Ganymede-X dressings.

Regulation Number	Device	Device Class	Product Code	Classification Panel
N/A	Ganymede (various sizes)	Unclassified	QSY	General & Plastic Surgery
N/A	Ganymede-X (various sizes)	Unclassified	QSY	General & Plastic Surgery

Common Name

Dressing – Hemostat

Trade/Proprietary Name:

Ganymede and Ganymede-X

Predicate

Quick Clot Z- Medica K123387
Product Code : QSY

Intended use and Indications

Over the counter:

Ganymede and Ganymede-X are intended for temporary external use to stop bleeding of superficial wounds, minor cuts, and abrasions.

Prescription Use:

Ganymede and Ganymede-X are intended to be used as a hemostatic dressing for local temporary management of moderately to severely bleeding wounds such as surgical wounds (operative, postoperative, dermatological), including junctional wounds not amenable to tourniquet use and traumatic injuries

Technological Characteristics and Summary of Substantial Equivalence:

As was established in this submission, the subject Ganymede/Ganymede-X dressings is substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States.

The subject devices, Ganymede and Ganymede-X, and the predicate device, QuikClot (K123387) have the same intended use, indications for use, and the same product code.

Substantial equivalence claims are being demonstrated for the QuikClot device and indications of QuikClot eX and not any other devices listed in the Ganymede and Ganymede-X 510(k) summary.

Ganymede and Ganymede-X are substantially equivalent to the predicate device, QuikClot and QuikClot eX with respect to design, structure, mechanism of action, intended use and indications.

Between the Ganymede and Ganymede-X dressing subject devices and the QuikClot predicate device the minor difference is a slight variation in material composition between the devices. The Ganymede and Ganymede-X devices are composed of purified clinoptilolite tuff in calcium alginate fibers blended with carboxymethyl cellulose and lyocell fibers. Ganymede-X includes an extra feature of a radiopaque yarn. QuikClot uses a layered clay hemostat, kaolin USP, which is bound to medical gauze using glycerin USP. The subject devices and predicate device both use medical grade non-woven fabric bound with a hemostatic agent. This aspect does not affect the safety or performance of the devices.

	Subject Devices	**Predicate Device**	**Reference Device**
Name	**Ganymede (including Ganymede-X)**	**QuikClot**	**QuikClot eX**
510(k) number	TBC	K123387	K072474
Manufacturer	Speciality Fibres and Materials Ltd	Z-Medica	Z-Medica
Product Code	QSY	QSY	QSY
Classification	Unclassified	Unclassified	Unclassified
For single use	Yes	Yes	Yes
Intended use	Over The Counter: Ganymede/Ganymede-X: Intended for temporary external use to stop bleeding of superficial wounds, minor cuts, and abrasions. Prescription Use: Ganymede/Ganymede-X: Intended to be used as a hemostatic dressing for local temporary management of moderately to severely bleeding wounds such as surgical wounds and traumatic injuries.	For use as a topical dressing for local management of bleeding wounds such as cuts, lacerations and abrasions. It may also be used for temporary treatment of severely bleeding wounds such as surgical wounds (operative, postoperative, dermatological, etc.) and traumatic injuries	Over The Counter: QuikClot eX is intended for temporary external use to stop bleeding of superficial wounds, minor cuts, and abrasions. Prescription Use: Temporary external use to control traumatic bleeding.
Indications for use	Over The Counter: Ganymede/Ganymede-X: Is intended for temporary external use to stop bleeding of superficial wounds, minor cuts, and abrasions Prescription Use: Ganymede/Ganymede-X: Intended for local temporary management of moderately to severely bleeding wounds such as: Surgical wounds (operative, postoperative,	For use as a topical dressing for local management of bleeding wounds such as cuts, lacerations and abrasions. It may also be used for temporary treatment of severely bleeding wounds such as surgical wounds (operative, postoperative, dermatological, etc.) and traumatic injuries	Over The Counter: QuikClot eX is intended for temporary external use to stop bleeding of superficial wounds, minor cuts, and abrasions. Prescription Use: Temporary external use to control traumatic bleeding.

	Subject Devices	Predicate Device	Reference Device
Name	**Ganymede (including Ganymede-X)**	**QuikClot**	**QuikClot eX**
	dermatological), including junctional wounds not amenable to tourniquet use and traumatic injuries		
OTC use?	Yes, for superficial wounds, minor cuts, and abrasions only.	No	Yes
Prescription use?	Yes	Yes	Yes
Use Environment	Clinical and home setting	Clinical setting	Clinical and home setting
Device Composition	Purified clinoptilolite tuff in calcium alginate fibers blended with carboxymethyl cellulose and lyocell fibers. Ganymede-X includes an x-ray detectable yarn added using Lyocell.	QuikClot Hemostatic gauze uses a layered clay hemostat, kaolin USP, which is bound to medical gauze using glycerin USP	QuikClot eX consists of standard non-woven medical gauze that has a clay mineral (Kaolin) bound to the gauze with Glycerin.
Design	Ganymede-X is a Purified clinoptilolite tuff and calcium alginate based hemostatic needle punched non-woven also containing carboxymethyl cellulose fibers and lyocell fibers. Ganymede-X includes an x-ray detectable yarn added using Lyocell.	QuikClot consists of standard non-woven medical gauze that has a clay mineral (Kaolin) bound to the gauze with Glycerin.	QuikClot eX consists of standard non-woven medical gauze that has a clay mineral (Kaolin) bound to the gauze with Glycerin.
Includes radiopaque yarn	Yes, Ganymede X contains radiopaque yarn	No	No
ISO 10993-1 Classification	Surface contact medical device that contacts breached and compromised skin, for a prolonged duration >24 hours to <30days.	Categorized as limited contact duration, external communicating device, tissue/bone/dentin communicating.	Categorized as limited contact duration, external communicating device, tissue/bone/dentin communicating.
Maximum Period of Use	72 hours	24 hours	24 hours
Single use	Yes	Yes	Yes
Method of sterilization	Gamma irradiation	Gamma irradiation	Gamma irradiation
Sizes	2cm diameter, 5cm x 5cm, 10cm x 10cm, 15cm x 15cm, 20cm x 20cm, 20cm x 30cm, 25cm x 25cm, 30cm x 30cm, 40cm x 40cm and 7.5cm x 120cm	Various, 1in (4cm) dia., 5/8in (1.6 cm) dia., 2in x 2in (5 cm x 5cm), 4in x 4in (10 cm x 10 cm), 12in x 12in (30.5 cm x 30.5 cm), 3in x 4yds (7.6 cm x	4 in x 4 in (10 cm x 10 cm)

	Subject Devices	Predicate Device	Reference Device
Name	**Ganymede (including Ganymede-X)**	**QuikClot**	**QuikClot eX**
		365.8 cm), 4in x 4yds (10 cm x 365.8 cm)	
Contraindications	**Ganymede/Ganymede-X (OTC)** • Not for use on heavily bleeding wounds • Not for use on deep wounds where the source of the bleeding is not seen • Not for surgical use or use on surgical wounds • Not for use on patients with known sensitivities to dressing components • The safety of Ganymede/Ganymede-X on all anastomoses (including vascular) and femoral artery puncture sites has not been established **Ganymede/Ganymede-X (Rx)** • Not for internal use • Not for use on patients with known sensitivities to dressing components • Not for use on axial wounds or on wounds not amenable to pressure • The safety of Ganymede on all anastomoses (including vascular) and femoral artery puncture sites has not been established	The safety and effectiveness of the QuikClot Hemostatic Dressing for use in neurological, ophthalmic, spinal, GI, orthopedic (bone repair), all anastomoses (including vascular) and femoral artery puncture sites have not been established.	The safety and effectiveness of the QuikClot eX Hemostatic Dressing for use in neurological, ophthalmic, spinal, GI, orthopedic (bone repair), all anastomoses (including vascular) and femoral artery puncture sites have not been established.

Description of the Device

Ganymede is a non-woven fabric comprised of carboxymethyl cellulose fibers, calcium alginate fibers containing Purified clinoptilolite tuff and Lyocell fibers. The Ganymede and Ganymede-X dressings are intended to be used as hemostatic dressings for local temporary management of traumatic injuries and severely and moderately bleeding wounds. The Ganymede-X dressing incorporates a strip of Micropake radiopaque yarn that has been stitch bonded to the fabric to aid identification under X-Ray. The devices are free from animal derived materials, non-exothermic, fast acting and highly absorbent. The mechanism of action is provided by the absorbent nature of the dressing components and the high calcium ion concentration.

Non-Clinical Tests

The results of these studies show that Ganymede and Ganymede-X equates to or exceeds the performance of the predicate device and does not introduce any new risks; therefore, the system is substantially equivalent to the predicate device.

The test results demonstrated that the proposed device complies with the following standards:

- ASTM D4169- 23
- ASTM D4332- 22
- ASTM F1886
- ASTM F1929
- ASTM F88
- BS EN ISO 13726

Animal Studies

In-vivo studies included within this submission confirm that Ganymede and Ganymede-X can perform as intended under anticipated conditions of use and demonstrates efficacy in achieving hemostasis in swine femoral artery wound models with severe bleeds. The performed bench testing reported that the Ganymede and Ganymede-X hemostatic dressings are substantially equivalent to the predicate device QuikClot, within this submission.

The following endpoints have been assessed in the safety and thrombogenicity of the dressing in a Swine vascular injury model study:

- Systemic Clinical Safety
- Thrombogenicity
- Particle migration
- Local tissue reaction
- Time to hemostasis
- Blood Loss
- Survival Rate
- Re-occurrence of bleeding

Biocompatibility Testing

Biocompatibility evaluation of Ganymede and Ganymede-X has been performed in order to determine the potential local tissue response and systemic toxicity and biocompatibility from contact of the component materials with the body. The evaluation has followed the guidance given in ISO-10993, “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing”

Category	Contact	Contact Duration	Minimum Endpoints
Surface-contacting devices	Breached or Compromised surfaces	Prolonged (>24 hrs, < 30 days)	• Physical and Chemical Information • Cytotoxicity • Sensitization • Irritation • Acute Systemic toxicity • Material mediated pyrogenicity • Subacute/Subchronic toxicity • Implantation Effects

As Ganymede and Ganymede-X are intended for the management of severely bleeding wounds, the following additional biological endpoints have also been considered:

- Genotoxicity
- Hemocompatibility

Consequently, SFM Ltd. demonstrated that its product is safe and biocompatible, fully compliant with the requirements of ISO 10993-1 and the FDA Guidance, - Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

Safety and Effectiveness Conclusion

Based on the information presented in these 510(k) premarket notifications, Ganymede and Ganymede-X are considered substantially equivalent to the QuikClot dressing. Ganymede and Ganymede-X devices are as safe and effective as the currently marketed predicate devices.

Based on testing and comparison with the predicate devices, Ganymede and Ganymede-X indicated no adverse indications or results. We have demonstrated that Ganymede and Ganymede-X are as safe as and as effective ,and perform within the design specifications and is substantially equivalent to the predicate device.