October 21, 2024

Speciality Fibres and Materials Ltd.
Nyerngoor Hewitt
Director of Regulatory Affairs and Quality
Galaxy House Binley Industrial Estate,
31 Herald Way
Coventry, West Midlands CV6 5SF
United Kingdom

Re: K222740
Trade/Device Name: Venus Ag 120 Wound Dressing with Antimicrobial Silver and Strengthening Cellulose Fiber. Venus Ag 160 Wound Dressing with Antimicrobial Silver and Strengthening Cellulose Fiber. Venus Ag 200 Wound Dressing with Antimicrobial Silver and Strengthening Cellulose Fiber.
Regulatory Class: Unclassified
Product Code: FRO
Dated: September 8, 2022
Received: September 9, 2022

Dear Nyerngoor Hewitt:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222740

Device Name
Venus Ag 120 Wound Dressing with Antimicrobial Silver and Strengthening Cellulose Fiber.
Venus Ag 160 Wound Dressing with Antimicrobial Silver and Strengthening Cellulose Fiber.
Venus Ag 200 Wound Dressing with Antimicrobial Silver and Strengthening Cellulose Fiber.

Indications for Use *(Describe)*

Under the supervision of a healthcare professional, Venus Ag may be used for the management of:

- wounds with moderate to heavy exudate
- partial thickness burns
- leg ulcers, pressure ulcers and diabetic ulcers
- surgical wounds (e.g. post-operative, wounds left to heal by secondary intent and donor/graft sites)
- traumatic wounds (e.g. abrasions and lacerations)
- wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided and donor sites.

The product is for a single use only.

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.

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510(k) Summary (Venus Ag)

Details of the device Venus Ag herewith applied for is as follows:

5.1 Administrative Information

Applicant	Speciality Fibres and Materials Limited, Galaxy House, Binley Industrial Estate, 31 Herald Way, Coventry CV3 2RQ, United Kingdom	
Official Correspondent and Contact Details	Nyerngoor Korda Hewitt Director of Regulatory Affairs and Quality Telephone: +44 (0) 2476 708 229, +44 (0) 7725 786 717 E-mail: nyerngoor.kordahewitt@sfm-limited.com	
Date Prepared	Initial 29 October 2021, 1st October 2024 Updated	
Device Details	**510(k) Number**	K222740
	Product Name(s)	Venus Ag 120 Wound Dressing with Antimicrobial Silver and Strengthening Cellulose Fiber. Venus Ag 160 Wound Dressing with Antimicrobial Silver and Strengthening Cellulose Fiber. Venus Ag 200 Wound Dressing with Antimicrobial Silver and Strengthening Cellulose Fiber.
	Classification Name	Unclassified
	Product Code	FRO
	Panel	General & Plastic Surgery
	Combination	Yes, the device is a combination product
Legally Marketed Predicate Device(s)	**Primary Predicate Device:** Titan Ag 200 K173844 **Additional Predicate Devices:** Aquacel Ag Extra K121275 Aquacel Ag+ Extra K173675 Kerracel Ag K162508	

5.2 Description of the Device

Venus Ag 120, 160 and 200 Wound Dressing with Antimicrobial Silver and Strengthening Cellulose Fiber are a soft, conformable non-woven fabrics made from sodium carboxymethyl cellulose and strengthening cellulose fiber(s) with antimicrobial silver. The silver in the wound dressing, when in contact with wound exudate or blood present in wound exudate, has an antimicrobial effect on bacteria held within the dressing, preventing it from being colonized. The absorption of exudate into the dressing forms a gel which assists in maintaining a moist wound environment, supporting autolytic debridement, protects the wound edge and surrounding skin from maceration. Through the gel formation the structure of the dressing remains intact. Debris and any bacteria found in the wound exudate can be retained inside the dressing and removed when the dressing is changed.
When dry, Venus Ag can easily be cut to the size of the wound.

The device is a combination product, code FRO.

Venus Ag dressings are supplied in a variety of sizes, configurations, and weights.

5.3 Indications for Use

Under the supervision of a healthcare professional, Venus Ag may be used for the

management of:

- Wounds with moderate to heavy exudate
- Partial thickness burns
- Leg ulcers, pressure ulcers and diabetic ulcers
- Surgical wounds (e.g. post-operative, wounds left to heal by secondary intent and donor/graft sites)
- Traumatic wounds (e.g. abrasions and lacerations)
- Wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided and donor sites

The product is for a single use only.

5.4 Summary of Technological Characteristics

Venus Ag technological characteristics are deemed comparable to those of the predicate devices. Venus Ag has the same intended use and general characteristics as the predicate devices as detailed in the table below. Minor technological differences are addressed in Table 5-1.

Table 5-1: Substantial Equivalence Comparison of Characteristics and Intended Use

Device Name	Venus Ag	Titan Ag 200	Aquacel Ag Extra	Aquacel Ag+ Extra	Kerracel Ag	Significant Differences / Justification for Equivalence
Manufacturer	**SFM Ltd**	**SFM Ltd**	**Convatec Inc**	**Convatec Inc**	**Crawford**	**N/A**
Identification	Subject Device	Primary Predicate Device	Additional Predicate Device	Secondary Predicate	Additional Predicate Device	N/A
510(k) Number	K222740	K173844	K121275	K173675	K162508	N/A
Product Code	FRO	FRO	FRO	FRO	FRO	Equivalent.
Regulation Name	Dressing, Wound, Drug	Dressing, Wound, Drug	Dressing, Wound, Drug	Dressing, Wound, Drug	Dressing, Wound, Drug	Equivalent.
Intended Use	Management of wounds with moderate to heavy exudate. The dressing absorbs wound exudate, forms a gel, and may retain bacteria in the wound exudate within the dressing. This ensures a moist wound healing environment. The dressing also has an antimicrobial action which is exerted by the silver released into the dressing.	Management of wounds with moderate to heavy exudate. The dressing absorbs wound exudate and may retain bacteria in the wound exudate within the dressing. This ensures a moist wound healing environment. The dressing contains silver, which limits the growth of bacteria within the dressing.	This conformable and highly absorbent dressing absorbs wound fluids, creating a soft gel which maintains a moist environment and supports the body's healing process.	This dressing absorbs wound fluid and creates a soft gel that conforms to the wound surface, maintains a moist environment and aids in the removal of non-viable tissue from the wound (autolytic debridement). A moist wound environment supports the body's healing process. The silver preservative in the dressing provides an effective barrier to bacterial penetration of the dressing as this may help reduce infection.	The silver in the dressing provides an antibacterial barrier that inhibits bacterial growth in the dressing for up to seven days. Absorbs high amounts of wound fluid and creates a soft cohesive gel that intimately conforms to the wound surface and maintains a moist wound healing environment.	Substantially Equivalent. Venus Ag has an Antimicrobial claim which is addressed in Section 18. Risk of infection are not within the scope of the Venus Ag indications.
Indications for Use	Management of wounds with moderate to heavy exudate	Management of wounds with moderate to heavy exudate	Management of wounds as an effective barrier to bacterial penetration of the dressing as this may help reduce infection	Aquacel Ag+ Extra dressings are indicated for:	Management of acute and chronic, partial and full thickness wounds including pressure ulcers, leg ulcers, diabetic foot ulcers, surgical wounds, traumatic wounds, first and second degree burns.	Equivalent to primary predicate. Malignant wounds in the additional predicate are not within the scope of the Venus Ag indications.
	Partial thickness burns	Partial thickness burns	Partial thickness (second degree) burns	Partial thickness burns		
	Leg ulcers, pressure ulcers and diabetic ulcers	Leg ulcers, pressure ulcers and diabetic ulcers	Diabetic foot ulcers, leg ulcers, (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology) and	Leg ulcers, including: Venous stasis ulcers Arterial ulcers. Legs ulcers of mixed aetiology Diabetic foot ulcers. Pressure ulcers/injuries		

Device Name	Venus Ag	Titan Ag 200	Aquacel Ag Extra	Aquacel Ag+ Extra	Kerracel Ag	Significant Differences / Justification for Equivalence
Manufacturer	**SFM Ltd**	**SFM Ltd**	**Convatec Inc**	**Convatec Inc**	**Crawford**	**N/A**
			pressure ulcers/sores (partial and full thickness);			
	Surgical wounds (e.g. post-operative wounds left to heal by secondary intent and donor/graft sites)	Surgical wounds (e.g. post-operative wounds left to heal by secondary intent and donor/graft sites)	Surgical wounds left to heal by secondary intention such as dehisced surgical incisions; Surgical wounds that heal by primary intent such as dermatological and surgical incisions (e.g. orthopedic and vascular)	Surgical wounds		
	Traumatic wounds (e.g. abrasions and lacerations)	Traumatic wounds (e.g. abrasions and lacerations)	Traumatic wounds	Traumatic wounds		
	Wounds that are prone to bleeding such as wounds that have been mechanically or surgically debrided and donor sites	Wounds that are prone to bleeding such as wounds that have been mechanically or surgically debrided and donor sites	Wounds that are prone to bleeding such as wounds that have been mechanically or surgically debrided and donor sites	Surgical wounds		
	-	-	Painful wounds; Infected wounds	-		
	-	-	-	Malignant wounds		
Contra indications	Should not be used on individuals who are sensitive to or who have had an allergic reaction to the dressing or its components.	Should not be used on individuals who are sensitive to or who have had an allergic reaction to the dressing or its components.	Should not be used on individuals who are sensitive to or who have had an allergic reaction to the dressing or its components.	Aquacel Ag+ Extra dressings should not be used on individuals who are sensitive to or have had an allergic reaction to silver, sodium carboxymethyl cellulose ethylenediaminetetraacetic acid di-sodium salt (EDTA) or benzethonium chloride (BECL).	Individuals with a known allergy or hypersensitivity to any of the components of KerraCel® Ag should not use the dressing.	Equivalent with primary device.

Prescription Use	Prescription Use	Prescription Use	OTC use Prescription Use	OTC use Prescription Use	Prescription Use	Equivalent with primary predicate device.
Maximum Period of Use	Seven days per dressing and maximum repeat dressings of 30 days	Seven days per dressing and maximum repeat dressings of 30 days	Seven days per dressing and maximum repeat dressings of 30 days	Aquacel Ag+ Extra dressings can be worn for up to seven days. Dressings should be changed earlier if clinically indicated. On partial thickness (second degree) burns, dressings may remain in place for up to 14 days. The requirement for Aquacel Ag+ Extra dressings should be re-assessed after 14 days and alternative wound management considered where appropriate.	The dressing can be left in place for up to seven days.	Equivalent with primary predicate device.

Device Name	Venus Ag	Titan Ag 200	Aquacel Ag Extra	Aquacel Ag+ Extra	Kerracel Ag	Significant Differences / Justification for Equivalence
Manufacturer	**SFM Ltd**	**SFM Ltd**	**Convatec Inc**	**Convatec Inc**	**Crawford**	**N/A**
Device Description	Soft, sterile, non-woven pad or ribbon dressing composed of sodium carboxymethyl cellulose, cellulose and silver which are blended by combining fibres in a carding and needling process.	Soft, sterile, non-woven pad or ribbon dressing composed of sodium carboxymethyl cellulose, cellulose and silver which are blended by combining fibres in a carding and needling process.	Soft, sterile, non-woven pad or ribbon dressing composed of sodium carboxymethylcellulose, which is incorporated in the form of a non-woven fleece held together by cellulose yarn using a stitch bonding process.	A soft, sterile dressing made from two layers of 1.2% ionic silver impregnated sodium carboxymethylcellulose fiber with added Ethylenediaminetetraacetic Acid Disodium Salt (EDTA) and Benzethonium Chloride and stitched together with strengthening fibers. The two Hydrofiber layers are nominally 77gsm (grams per square meter) weight each. Aquacel Ag+ also includes added Ethylenediaminetetraacetic Acid Disodium Salt (EDTA) and Benzethonium Chloride (BECL). See foot note 2.	Soft, sterile, nonwoven wound dressing made of sodium carboxymethyl cellulose (CMC), cellulose fibers, and silver.	Equivalent (see discussion in footnote 5).
Silver Content	18mg/100cm²	7mg/100cm²	23mg/100cm²	1.3 % w/w (Approx. 22mg/100cm²)	20mg/100cm²	Venus Ag has a higher silver content than the Titan Ag 200; this increase in silver content does not affect the safety profile or the in vivo activity as substantiated by the biocompatibility studies performed with the subject device, as well the effectiveness of the device, as substantiated by the substantial equivalence analysis. Both Venus Ag and Titan Ag release ionic silver from silver nanoparticles. The additional predicate devices Aquacel Ag Extra and Aquacel Ag + Extra demonstrate that ionic silver used at the percentage of 1.3%w/w (23mg/100cm2) is safe and Kerracel Ag demonstrates that ionic silver used at the

						percentage of 1.7%w/w (20mg/100cm2) is safe. Venus Ag has ionic silver at 1.5% w/w (18mg/100cm2) which is less. The safety and performance are further supported by the in vivo and in vitro tests and the antimicrobial test. The safety testing of the nanoparticle silver confirmed that the concentration of 18mg/100cm2 used in this device is safe.

Device Name	Venus Ag	Titan Ag 200	Aquacel Ag Extra		Kerracel Ag	Significant Differences / Justification for Equivalence
Manufacturer	**SFM Ltd**	**SFM Ltd**	**Convatec Inc**		**Crawford**	**N/A**
Antimicrobial Agent	Ionic silver released from elemental silver nanoparticles within the dressing.	Ionic silver released from elemental silver nanoparticles within the dressing.	Ionic silver released form silver compounds within the dressing.	Ionic silver released form silver compounds within the dressing.	Silver ions released from silver oxysalts (Ag7NO11) within the dressing.	Equivalent to primary predicate device. Both Venus Ag and Titan Ag antimicrobial agent is ionic silver released from elemental silver nanoparticles within the dressing, while Aquacel Ag Extra releases ionic silver from silver compounds within the dressing, and Kerracel Ag release silver ions from silver oxysalts within the dressing. The agent in each case works through the release of silver ions into the

Device Name	Venus Ag	Titan Ag 200	Aquacel Ag Extra		Kerracel Ag	Significant Differences / Justification for Equivalence
Manufacturer	**SFM Ltd**	**SFM Ltd**	**Convatec Inc**		**Crawford**	**N/A**
						dressing. The silver ions released in a moist environment from nanoparticles or silver salts are identical. Therefore, the difference in silver composition between Venus Ag and the predicates (Titan Ag, Aquacel Ag Extra and Kerracel Ag) do not impact safety and performance as substantiated by the biocompatibility reports and the substantial equivalence analysis.
Sterilisation	Sterile (Gamma)	Sterile (Gamma)	Sterile (Gamma)	Sterile (Gamma)	Sterile (Gamma)	Equivalent.
Packaging	Foil	Paper pouch	Foil	Foil	Foil	The foil pouch used is equivalent to the pouch used in the additional predicate Kerracel Ag and Aquacel Ag Extra. Studies on packaging integrity and accelerated aging demonstrated the packaging is appropriate for maintaining device integrity and sterility.
Single-Use	Single-Use	Single-Use	Single-Use	Single-Use	Single-Use	Equivalent.

5.5 Summary of Non-Clinical and Clinical and Performance Data

The following standards were adhered to during performance testing:

- **ISO 10993-1:2018,** Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

5.5.1 Performance Testing (Bench)

- **Antimicrobial efficacy** according to modified AATCC 100 was found to consistently meet requirement of a log 4 reduction within the dressing when compared to a control against gram-negative, gram-positive, yeast and mould.
- **Silver release profile** within the dressing was found to be equivalent to that of the predicate device in simulated wound fluid over 24 hours, 5 days and 7 days.
- The **silver content** of the product remains at the same silver content throughout accelerated and real-time stability studies, therefore the release profile within the dressing is not tested at all time-points as no change is expected.
- **Absorbency** according to British Pharmacopoeia; Test Method for absorbency of Alginate dressings/Surgical dressings, and European Standard EN13726-1 and product consistently meets specifications.
- **Tensile strength** according to British Pharmacopoeia meets the specifications set for this product
- **Stability Studies**

5.5.2 Biocompatibility Testing

Venus Ag devices are classified as surface devices with prolonged use (>24h to 30 days) and the relevant Biocompatibility studies were performed.

The following testing was conducted to demonstrate that the proposed device is as safe as the cleared 510(k) predicate device. Biocompatibility testing was conducted according to ISO 10993-1:

- **Cytotoxicity** according to *ISO 10993-5, Biological Evaluation of Medical Devices, Part 5; Tests for In Vitro Cytotoxicity*
- **Intracutaneous Irritation studies** according to *ISO 10993-10, Biological Evaluation of Medical Devices, Part 10; Tests for Irritation and skin sensitization*
- **Acute Systemic Toxicity** according to *ISO 10993-11, Biological Evaluation of Medical Devices, Part 11; Tests for Systemic Toxicity*
- **Sub-acute Systemic Toxicity and Implantation** according to *ISO 10993 standards: Biological Evaluation of Medical Devices, Part 2: Animal welfare requirements, Part 6: Tests for local effects after implantation and Part 11: Tests for Systemic Toxicity*
- **Sensitization** according to *ISO 10993-10, Biological Evaluation of Medical Devices, Part 10; Tests for Irritation and skin sensitization*

- **Material Mediated Pyrogenicity** *ISO 10993-11, Biological evaluation of medical devices, Part 11*; Tests for systemic toxicity according to *United States Pharmacopoeia (USP) 42 – National Formulary 37*. And *European Pharmacopeia, 10th edition*
- **Biological and Toxicological Risk Assessment** according to *ISO 10993-17 Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances*

The performance studies indicate that Venus Ag wound dressings does not raise new questions regarding safety or performance with respect to the predicate device and is safe for its indication for use.

The non-clinical testing detailed in this submission supports the substantial equivalence of the subject device to the predicate device.

5.5.3 Performance Data (Animal)

A porcine wound healing study was conducted in accordance with ISO 10993-6 with a comparison to a legally marketed device. Venus Ag was tested alongside the predicate device Aquacel Ag+ Extra, as well as one control dressing. Overall, Venus Ag did not impair the wound healing process as observed from the various histology parameters analyzed and as compared to the predicate.

5.5.4 Performance Data (Clinical)

No clinical testing was required to support substantial equivalence.

5.6 Non-Performance Testing

The following testing was conducted to ensure the integrity of the end product:

- **Sterilisation Validation** according to ISO 11137-1 and ISO 11137-2. Sterilisation of health care products, and results confirmed that Venus Ag successfully met its predetermined acceptance criteria as per standards.
- **Packaging Validation and Integrity Testing** according to ASTM F1886/ F1886M Standard test Method for determining Integrity of Seals for Flexible Packaging by Visual Inspection, ASTM F1929, ASTM F1929 Standard test Method for Detecting Seal Leak, ASTM F88/ F88M Standard test method for Seal Strength of Flexible Barrier Materials and Venus Ag successfully met its predetermined acceptance criteria as per standards.
- **Shelf-life Testing** - A maximum shelf life of 24 months (based on real time aged Final Finished Device) has been assigned when stored unopened at ambient temperature, in accordance with the manufacturer's recommendations.

5.7 Statement of Substantial Equivalence

Venus Ag (subject device, K222740) is substantially equivalent to the cleared primary predicate device Titan Ag 200 (K173844) and supporting additional predicate devices Aquacel Ag Extra (K121275), Aquacel Ag+ Extra K173675 and Kerracell Ag (K162508).

Venus Ag's equivalence is based on the following:

- It has the same intended use as the primary predicate device; and displays performance equivalent to that of the predicate device.
- It has the same composition of carboxymethyl cellulose, regenerated cellulose and ionic silver released into dressing as the primary predicate device.
- The minor technological characteristic differences, compared to the primary predicate, do not influence the substantial equivalence.

With the information included in this section, we aim to summarise the information used to:

- demonstrate that the device applied for raises no concerns in terms of device performance and,
- demonstrate that the device is at least as safe and effective as the legally marketed predicate device.

The data provided demonstrates that there are no new questions of safety and effectiveness compared to the predicate, and the subject device is substantially equivalent to the predicate device.