August 9, 2018

Speciality Fibres and Materials Ltd.
Lindie Turvey
Senior Regulatory Affairs Officer
101 Lockhurst Lane
Coventry, CV6 5SF
United Kingdom

Re: K173844
Trade/Device Name: Titan Ag 200
Regulatory Class: Unclassified
Product Code: FRO
Dated: December 14, 2017
Received: December 19, 2017

Dear Lindie Turvey:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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510(k) Summary
K173844

Details of the device **Titan Ag 200** herewith applied for is as follows:

5.1 ADMINISTRATIVE INFORMATION

Submitted by:	Speciality Fibres and Materials Limited. 101 Lockhurst Lane, Coventry, CV6 5SF, United Kingdom **Establishment Registration No**.: 3005818605	
Contact details:	Lindie Turvey Regulatory Affairs Officer Telephone: +44 (0)2476 708 253 or +44 (0)73 79 333 207 Fax: +44 (0) 2476 682737 E-mail: Lindie.turvey@sfm-limited.com	
Date prepared:	6 July 2018	
Device Details:	Trade Name:	Titan Ag 200
	Classification Name:	Dressing, Wound, Drug
	Common Name:	Wound Dressing with antibacterial silver and strengthening cellulose fibre
	Product Code:	FRO
	Classification:	Unclassified
	Panel:	General & Plastic Surgery
Legally Marketed Predicate Device(s):	Aquacel Ag Extra, 510(k) No. K121275	
Legally Marketed Reference Devices	Ross Ru Wound Dressing Gel (K162017) Acticoat Flex 7 (K083113) Opticell Ag (K100693) Durafiber Ag (K103793/K161289)	

5.2 DESCRIPTION OF THE DEVICE:

Titan Ag 200 Wound Dressing is a soft, conformable non-woven fabric made from a blend of cellulose fiber(s) impregnated with metallic silver (in the form of silver nano-particles), sodium carboxymethyl cellulose fibres and strengthening cellulose fiber(s). The ionic silver released into the wound dressing when in contact with wound exudate or blood has an antibacterial effect on wound bacteria held within the dressing, preventing it from being colonized. The structure of the dressing remains intact through the gel formation. Debris and any bacteria absorbed in the wound exudate and retained within the dressing are removed when the dressing is changed.

Exudate is absorbed into the dressing. In addition, the dressing assists in maintaining a moist wound environment, supports autolytic debridement, and protects the wound edge and surrounding skin from maceration, thus supporting the healing process.

5.3 INDICATIONS FOR USE:

Under the supervision of a healthcare professional, Titan Ag 200 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 prone to bleeding such as wounds that have been mechanically or surgically debrided or donor sites .

5.4 SUMMARY OF TECHNOLOGICAL CHARACTERISTICS:

The **Titan Ag 200** technological characteristics are deemed comparable to those of the predicate device.

Important technological characteristics of Titan Ag 200 to consider are the presence of antibacterial silver in the dressing which reduces bacterial growth within the dressing. and the absorbency capacity of the dressing when compared to the predicate device, as these characteristics constitute the mode of action of the device. Therefore, the chosen predicate device is composed of the same material (carboxymethyl cellulose and regenerated cellulose) as the **Titan Ag 200**, shares the ability to absorb and retain wound fluid together with any bacteria and wound debris that may be present in the fluid, and has an equivalent silver release pattern into the dressing. The results of testing are summarised below. Based on the evidence generated the **Titan Ag 200** releases silver ions into the dressing and not silver nanoparticles.
Titan Ag 200 has the same intended use and general characteristics as the predicate device as detailed in the table below. Minor technological differences are addressed in the tables below.

Table 5-1 Substantial Equivalence Comparison of Characteristics and Intended use

Manufacturer	**Convatec inc**	**Speciality Fibres and Materials Ltd.**	**Comparison**
Trade Name	**Aquacel Ag Extra**	**Titan Ag 200**	
510(k) Number	**K121275 (Predicate Device)**	**K173844 (Subject Device)**	
Product Code	FRO	FRO	Equivalent
Regulation Name	Dressing, Wound Drug	Dressing, Wound Drug	Equivalent

510(k) Number	K121275 (Predicate Device)	K173844 (Subject Device)	Comparison
Intended use	Management of wounds with moderate to heavy exudate. The dressing absorbs wound exudate and forms a gel which retains the bacteria laden wound exudate in 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.	Equivalent. As per FDA recommendations we wish to only claim antibacterial action in-line with the available data.
Indications for Use	Management of wounds as an effective barrier to bacterial penetration of the dressing as this may help reduce infection	Management of wounds with moderate to heavy exudate	Equivalent
	Partial thickness (second degree) burns	Partial thickness burns	
	Diabetic foot ulcers, leg ulcers, (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology) and pressure ulcers/sores (partial and full thickness);	Leg ulcers, pressure ulcers and diabetic ulcers	
	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 (e.g. post-operative wounds left to heal by secondary intent and donor/graft sites)	
	Traumatic wounds	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;	Wounds prone to bleeding such as wounds that have been mechanically or surgically debrided or donor sites	
	Painful wounds; Infected 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.	Equivalent

Prescription Use	OTC use Prescription Use	Prescription Use Only	SFM will apply more stringent use until enough post marketing surveillance data becomes available. A separate 510(k) will be submitted in the event of extending use to OTC
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	Equivalent
Device description [1]	Soft, sterile, non-woven pad or ribbon dressing composed of sodium carboxymethylcellulose containing silver, which is incorporated in the form of a non-woven fleece held together by cellulose yarn using a stich bonding process.	Soft, sterile, non-woven pad or ribbon dressing composed of sodium carboxymethylcellulose, cellulose and silver which are blended by combining fibres in a carding and needling process.	Equivalent
Silver content	1.3 % m/m 1.3 mg silver per 10x10 cm dressing	0.35% m/m 0.35 mg silver per 10cm x 10cm dressing	The subject device has a lower silver content than the predicate device. This is because the use of silver nanoparticles that have a high surface area to weight ratio provides a rate of sustained release of silver ions into the dressing that is comparable to that of the predicate device. This is substantiated by in vitro test data and antibacterial effectiveness test data.
Active anti-bacterial agent	Ionic silver released from silver compounds	Ionic silver released from elemental silver nanoparticles	Equivalent
Sterile	Sterile (Gamma)	Sterile (Gamma)	Equivalent
Packaging	Foil	Paper pouch	Although the packaging material differs, studies on packaging integrity and accelerated aging demonstrated the packaging is appropriate for maintaining device

			integrity and sterility.
Shelf Life	Three years	12months	N/A
Re-enforcing fibres [3]	Regenerated cellulose fibres 18%	Regenerated cellulose fibres 40%	The subject device and predicate device have substantially the same composition with a majority of the product comprising sodium carboxymethyl cellulose fibres. The difference in the percentage of gel forming carboxymethyl cellulose fibres does not affect the performance of the devices as shown by testing. The method of reinforcement is a difference between the two devices. SFM have chosen to increase the strength of the subject device by homogenously blending regenerated cellulose fibres in the non-woven fabric. The biological risk of the additional cellulose content was considered as part of the risk assessment
Absorbent gel forming fibres	Sodium carboxymethyl cellulose	Sodium carboxymethyl cellulose	Equivalent

Reference Device comparison			
510(k) Number	K121275 (Predicate Device)	K173844 (Subject Device)	Comparison
Reference Device 1	**Durafiber Ag** **K103793/K161289** **Description:** DURAFIBER Ag is a non-woven dressing made of cellulose and cellulose ethylsulphonate with silver. The product is an absorbent fibrous dressing that gels on contact with wound fluid. The silver provides the antimicrobial properties intended to reduce or inhibit microbial colonization of the device. The silver is present in the device in the form of silver chloride. Upon contact with wound fluid, silver ions are produced from the dissociation of silver and chloride atoms. The ionic form of silver is the active antimicrobial agent. **Blending technology:** Standard non-woven technology, e.g. carding and cross folding. **Dressing material:** Cellulose and cellulose ethylsulphonate with silver.	**TITAN Ag 200** **K173844** **Description** Non-woven dressing made of carboxymethyl cellulose, cellulose and cellulose with silver. The product is an absorbent fibrous dressing that gels on contact with wound fluid. The silver provides the antibacterial properties intended to reduce or inhibit bacterial colonization of the device. The silver is present as PVP capped silver particles. Silver ions are produced from silver particles on contact with wound fluid. The ionic form of silver is the active agent. **Blending technology:** Standard non-woven technology, e.g. carding and cross folding. **Dressing material:** Carboxymethyl cellulose with strengthening cellulose fibres	Similar blending technology but difference in materials
Reference Device 2	**Opticell Ag** **K100693** **Description** A soft, sterile, non-woven pad or ribbon dressing. The dressing is comprised of chitosan, chitosan derivatives and structural materials with the addition of ionic silver.	**Titan Ag 200** **K173844** **Description** Non-woven dressing made of carboxymethyl cellulose, cellulose and cellulose with silver. The product is an absorbent fibrous dressing that gels on contact with wound fluid. The silver provides the antibacterial properties intended to reduce or inhibit bacterial colonization of the device.	Similar blending technology but difference in materials

Reference Device comparison			
510(k) Number	K121275 (Predicate Device)	K173844 (Subject Device)	Comparison
		The silver is present as PVP capped silver particles. Silver ions are produced from silver particles on contact with wound fluid. The ionic form of silver is the active agent. **Blending technology:** Standard non-woven technology, e.g. carding and cross folding. **Dressing material:** Carboxymethyl cellulose with strengthening cellulose fibres	
	Blending technology: Unknown – believed to be via standard non-woven technology, e.g. carding and cross folding. **Dressing material:** Chitosan, chitosan derivatives and structural materials with ionic silver		
Reference Device 3	**Acticoat Flex** **K083113** **Device description:** Effective antimicrobial barrier dressings. The Nanocrystalline silver coating rapidly kills a broad spectrum of bacteria in as little as 30mins. ACTICOAT Flex 3 & 7 consist of a single layer of knitted polyester to ensure ultimate flexibility and comfort during wear time for the patient. **Silver content** Nano-crystaline silver unknown concentrations **Silver release** Mechanism unknown	**Titan Ag 200** **K173844** **Device description:** Non-woven dressing made of carboxymethyl cellulose, cellulose and cellulose with silver. The product is an absorbent fibrous dressing that gels on contact with wound fluid. The silver provides the antibacterial properties intended to reduce or inhibit bacterial colonization of the device. The silver is present as PVP capped silver particles. Silver ions are produced from silver particles on contact with wound fluid. The ionic form of silver is the active agent. **Silver content** Silver-nanoparticles (0.35%) **Silver release** PVP-capped silver nanoparticles release silver ions when in contact with wound fluid	Similar intended use.

Reference Device comparison			
Reference Device 4	**Ross Ru Wound Dressing Gel K092826** **Description** Ross Ru is a wound dressing gel that helps maintain a moist wound environment that is conducive to healing, by either absorbing or donating the moisture and wound exudates. Ross Ru Wound Dressing Gel is supplied in a collapsible low density polyethylene tube sealed at one end and fitted with a dispensing orifice at the other end accessible by the removal of its screw cap. **Materials** Purified water, nano-silver at 0.1 micron, TEA, carbopol, propylene glycol	**Titan Ag 200 K173844** **Device description:** Non-woven dressing made of carboxymethyl cellulose, cellulose and cellulose with silver. The product is an absorbent fibrous dressing that gels on contact with wound fluid. The silver provides the antibacterial properties intended to reduce or inhibit bacterialcolonization of the device. The silver is present as PVP capped silver particles. Silver ions are produced from silver particles on contact with wound fluid. The ionic form of silver is the active agent. **Materials** PVP-capped nano-silver ,carboxymethylcellulose dressings and cellulose fibres	Both dressings contain nano-silver

Footnotes and discussion of equivalence

1 **Construction of dressings**

There is a minor difference in the methods of constructing the dressings between the predicate and subject device. The predicate device is, SFM believe, created by a process of carding and needling fibres into a web before bonding two webs together by a stitch bonding process. The subject device dressing is created by a process of blending fibres and then carding and needling them into a dressing. This fibre blending process is used for other FDA 510(k) cleared devices.

5.5 SUMMARY OF NON-CLINICAL AND CLINICAL PERFORMANCE DATA:

The following standards were adhered to during performance testing

- **ISO 10993-1 (2009/Cor1: 2010):** *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process,*[i]
- **EN ISO 14971 (2012)/ISO 14971 (2007):** *Medical Devices – Application of risk management to medical devices, Annex I: Guidance on Risk Analysis Procedures for Biological Hazards,*[ii]

- **ISO/TR 15499 (2012):** *Biological evaluation of medical devices — Guidance on the conduct of biological evaluation within a risk management process,*[iii]
- The European Union Medical Device Directive 93/42/EEC amended 2007/47/EC,[iv]

The critical performance characteristics of the predicate and subject device are compared in the table below.

Table 5-2 Substantial Equivalence Comparison of Performance Characteristics

Performance Characteristics			
Manufacturer	**Convatec inc**	**Speciality Fibres and Materials Ltd.**	**Comparison**
Trade Name	**Aquacel Ag Extra**	**Titan Ag 200**	
510(k) number	**K121275** **Predicate device**	**K173844** **Test device**	
Mode of action	Releases silver ions on contact with wound exudate. Absorbing wound exudate and forming a gel trapping debris and bacteria in the dressing	Releases silver ions on contact with wound exudate. The silver ions are released into the wound dressing, but not into the wound bed. Absorbing wound exudate and forming a gel trapping debris and bacteria in the dressing	Equivalent
Silver Release [4]	2420-4250 ppb / 24hrs ***0.021 -0.031 mg/ 10cm^2/24 hrs***	2880-3560 ppb/24hrs 24 – 30 ppm/10 cm^2 /24 hrs ***0.025-0.030mg /10cm^2/24 hrs***	Similar Statistical analysis of the difference in results obtained for silver release over 7 days for the subject and predicate devices was statistically insignificant. Therefore the devices are deemed to have equivalent silver release. . It should be noted that the 120gsm and 200 gsm products have a similar silver release profile.
Absorbency	24g/100cm²	30g/100cm²	Equivalent

Performance Characteristics			
Antibacterial activity	Assumed to meet the criteria of a > 4 log reduction	Log reduction for various bacteria at corresponding time-points > 4.	Meets requirement: Antibacterial activity remains above the log reduction of 4, which confirms the effectiveness of the device for its the intended use.
Wet tensile Strength	15.9 N/cm	3 – 5.9 N/cm	Equivalent
Biocompatibility	Assumed to pass the requirements of applicable ISO 10993 tests	Comprehensive biocompatibility testing confirmed that the device raises no safety concerns.	Meets requirement. The biocompatibility of Titan Ag 200 has been demonstrated in accordance with FDA Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

5.5.1 Discussion on Performance testing

Performance testing was done according to standards where an accepted industry standard exists:

- **Antibacterial efficacy** according AATCC 100 was found to consistently meet requirement of a log 4 reduction when compared to a control
- **Silver release** profile was found to be similar than that of the predicate device in similated wound fluid over 7 days**.**
- **Absorbancy** according to British Pharmacopoeia; Test Method for absorbency of Alginate dressings/Surgical dressings, and European Standard EN13726-1 March 2002 and product consistently meets specifications.
- **Wet Tensile strength** according to British Pharmacopoeia meets the specifications set for this product and displays a strength better than that of the predicate device.

5.5.2 Discussion on Biocompatibility Testing

Titan Ag 200 is classified as a surface device with prolonged use and the relevant biocompatibility studies were performed.

Biocompatibility testing was conducted according to ISO 10993-1- 2009 and the following concluded.
Testing included:

- **Toxicological Risk Assessment** according to ISO 10993-17 Biological evaluation of medical devices -- Part 17: Establishment of allowable limits for leachable substances, overall, it was concluded that the detected extractables would not pose significant health risks to patients, even if they were to be genuine leachables from the dressing, reach the patients, and be entirely absorbed into the blood stream.
- **Acute systemic toxicity** according to ISO 10993-11, Biological Evaluation of Medical Devices, Part 11; Tests for Systemic Toxicity and Under the conditions of this study, there was no evidence of significant systemic toxicity or mortality after test article extracts injection
- **Sub-acute Systemic Toxicity** according to ISO 10993 standards: Biological Evaluation of Medical Devices, Part 2 (2006): Animal welfare requirements, Part 6 (2007): Tests for local effects after implantation and Part 11 (2006): Tests for Systemic Toxicity, there was no evidence of adverse systemic toxicity or local effects that could be attributed to Titan Ag 200 following repeated topical applications
- **Irritation studies** according to ISO 10993-10, Biological Evaluation of Medical Devices, Part 10; Tests for Irritation and skin sensitization, met the requirements of the intracutaneous injection test in the rabbit.
- **Cytotoxicity** according to ISO 10993-5, Biological Evaluation of Medical Devices, Part 5; Tests for In Vitro Cytotoxicity test article extract showed no cytotoxicity potential to L-929 mouse fibroblast cells.
- **Sensitisation** according to ISO 10993-10, Biological Evaluation of Medical Devices, Part 10; Tests for Irritation and skin sensitization and the test article was not considered a sensitizer in the guinea pig maximization model.
- **Material mediated pyrogenicity** ISO 10993-11 according to United States Pharmacopoeia (USP) 39 – National Formulary 34. And European pharmacopeia, 8th edition and the article was judged non-pyrogenic
- **Genotoxicity** according to ISO 10993-3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity test article extracts were considered to be non-mutagenic

The overall Biological risk assessment was conducted using the following standards and it was concluded that Titan Ag 200 Antibacterial Wound Dressing is considered to be a biocompatible medical device, with respect to ISO 10993 and US FDA (2016) guidance, when applied for its intended use.

International Standard ISO 10993 series. Biological evaluation of medical devices.

- International Standard ISO 10993-1. Biological evaluation of medical devices. Part 1: Evaluation and testing within a risk management process (ISO, 2009a).
- Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (EC, 1993) asamended, together with relevant guidance.
- Use of International Standard ISO 10993-1, "Biological evaluation of medical devices. Part 1: Evaluation and testing within a risk management process." Guidance for Industry and Food and Drug Administration Staff. Document issued on June 16, 2016 (US FDA, 2016).

The performance studies indicate that **Titan Ag 200** wound dressing does not raise new questions in regards to safety or effectiveness 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 Discussion on Performance data (Animal)

A porcine wound healing study with a comparison to a legally marketed device, the chosen predicate Aquacel Ag Extra was performed. Overall it was concluded that Titan Ag did not impair the wound healing process.

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 EN ISO 11137-2. Sterilisation of health care products, and results confirmed that Titan Ag successfully met its predetermined acceptance criteria as per standards
- **Packaging 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 Titan Ag 200 successfully met its predetermined acceptance criteria as per standards
- **Shelf-life testing** - A maximum shelf life of 12 months has been assigned when stored unopened at ambient temperature, in accordance with the manufacturer's recommendations.

5.7 STATEMENT OF SUBSTANTIAL EQUIVALENCE:

The subject device, **Titan Ag 200,** described in this submission is substantially equivalent to the predicate device **Aquacel Ag Extra** (K121275)

Titan Ag 200:

- has the same intended use as the predicate; and displays performance equivalent to that of the predicate device.
- has the essentially same composition of carboxymethyl cellulose, regenerated cellulose and ionic silver released into dressing.
- minor technological characteristic differences to the predicate, which 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.