September 8, 2023

Syntex Healthcare Products Co., Ltd.
% Kathy Liu
Project Manager
Hongray(USA) Medical Products Inc.
3973 Schaefer Avenue
Chino, California 91710

Re: K231643
Trade/Device Name: Biodegradable Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, OPJ, QDO
Dated: June 5, 2023
Received: August 7, 2023

Dear Kathy Liu:

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/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 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 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,

Allan Guan -S

For Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231643

Device Name
Biodegradable Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue)

Indications for Use *(Describe)*
The glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. Gloves have been tested for use with chemotherapy drugs and Fentanyl Citrate using ASTM D6978-05(2019)

Chemotherapy Drug	Minimum BDT (Minutes)
Azacytidine (Vidaza) 25 mg/ml (25000ppm)	>240
Bleomycin Sulfate 15mg/ml (15000 ppm)	>240
Busulfan 6mg/ml (6,000 ppm)	>240
Carboplatin 10mg/ml (10,000 ppm)	>240
Carmustine (BCNU)3.3 mg/ml (3,300 ppm)	12.9
Chloroquine 50mg/ml (50,000ppm)	>240
Cisplatin 1mg/ml (1,000 ppm)	>240
Cyclophosphamide 20mg/ml (20,000 ppm)	>240
Cyclosporin A 100 mg/ml (100,000 ppm)	>240
Cytarabine HCL, 100 mg/ml (100,000 ppm)	>240
Dacarbazine 10 mg/ml (10,000 ppm)	>240
Daunorubicin HCL, 5 mg/ml (5,000 ppm)	>240
Docetaxel, 10 mg/ml (10,000 ppm)	>240
Doxorubicin HCL, 2 mg/ml (2,000 ppm)	>240
Etoposide, 20 mg/ml (20,000 ppm)	>240
Epirubicin HCL, 2 mg/ml (2,000 ppm)	>240
Fludarabine, 25 mg/ml (25,000 ppm)	>240
Fluorouracil, 50mg/ml (50,000ppm)	>240
Gemcitabine, 38mg/ml (38,000ppm)	>240
Idarubicin HCL, 1mg/ml (1,000ppm)	>240
Ifosfamide, 50mg/ml (50,000ppm)	>240
Irinotecan, 20mg/ml (20,000ppm)	>240
Mechlorethamine HCI, 1mg/ml (1,000ppm)	>240
Melphalan, 5mg/ml (5,000ppm)	>240
Methotrexate, 25mg/ml (25,000ppm)	>240
Mitomycin C, 0.5mg/ml (500ppm)	>240
Mitoxantrone HCL, 2mg/ml (2,000ppm)	>240
Oxaliplatin, 5mg/ml (5,000ppm)	>240
Paclitaxel, 6mg/ml (6,000ppm)	>240
Paraplatin, 10mg/ml (10,000ppm)	>240
Retrovir, 10mg/ml (10,000ppm)	>240
Rituximab, 10mg/ml (10,000ppm)	>240
Thio Tepa, 10mg/ml (10,000ppm)	35.6
Topotecan, 1mg/ml (1,000ppm)	>240
Trisenox, 1mg/ml (1,000ppm)	>240
Velcade (Bortezomib), 1mg/ml (1,000ppm)	>240
Vincristine Sulfate (Oncovin), 1mg/ml (1,000ppm)	>240
Vinorelbine, 10 mg/ml (10000ppm)	>240

Fentanyl Citrate		Minimum BDT Minutes
Fentanyl Citrate Injection	(100 mcg/2ml)	>240

*Please note that the following drugs have extremely low permeation times:
Carmustine: 12.9 minutes, Thio Tepa: 35.6 minutes
Warning: Do not use with Carmustine and Thio Tepa.

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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Syntex Healthcare Products Co., Ltd.

No. 1, Fanjiazhuang Industrial Zone, Xinji City,
Hebei Province, 052360, China

510K Summary K231643

Date Prepared: September 07, 2023

1. Owner's Identification:

Mr. Qiao Zhiqiang
Syntex Healthcare Products Co., Ltd
No. 1, Fanjiazhuang Industrial Zone, Xinji City, Hebei Province, 052360, China
Tel:86-311-66179668
Contact: Ms. Kathy Liu, Project Manager
Address: 3973 Schaefer Avenue, Chino, CA 91710, USA Tel:909-590-1611
Email: fdareg@hongray.com.cn or janicema@hongrayusa.com

2. Name of the Device:

Trade / Product Name: Biodegradable Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue)
Common Name: Exam Gloves
Classification Name: Patient Examination Glove Specialty Classification
Regulation: 21 CFR 880.6250
Product Code: LZA, LZC, OPJ, QDO
Classification Panel: General Hospital
Device Class: Class I

3. Predicate Device Information:

Primary Predicate Device:
Hartalega NGC SDN. BHD.
Biodegradable Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue) (K200581)

Reference Device:
Better Care Plastic Technology Co., Ltd.
Powder Free Nitrile Examination Gloves (Blue) Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (K221269)

4. Device Description:

Biodegradable Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue) are Class I Patient Examination Gloves and Specialty Chemotherapy Gloves. They are ambidextrous and come in different sizes - Extra Small, Small, Medium, Large, Extra Large and XXL. Gloves meet the specification of ASTM D6319-19 and have been tested for resistance to permeation by chemotherapy drugs and Fentanyl Citrate as per ASTM D6978-05(2019). The gloves are single use, disposable, and provided non-sterile. The glove has biodegradation property tested per ASTM D5511. Biodegradability is not a medical claim and therefore was not reviewed by the FDA.

5. Indications for Use:

The glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent

contamination between patient and examiner.
Gloves have been tested for use with chemotherapy drugs and Fentanyl Citrate using ASTM D6978-05(2019)

Chemotherapy Drug	Minimum Breakthrough Detection Time (Minutes)
Azacytidine (Vidaza) 25 mg/ml (25000ppm)	>240
Bleomycin Sulfate 15mg/ml (15000 ppm)	>240
Busulfan 6mg/ml (6,000 ppm)	>240
Carboplatin 10mg/ml (10,000 ppm)	>240
Carmustine (BCNU)3.3 mg/ml (3,300 ppm)	12.9
Chloroquine 50mg/ml (50,000ppm)	>240
Cisplatin 1mg/ml (1,000 ppm)	>240
Cyclophosphamide 20mg/ml (20,000 ppm)	>240
Cyclosporin A 100 mg/ml (100,000 ppm)	>240
Cytarabine HCL, 100 mg/ml (100,000 ppm)	>240
Dacarbazine 10 mg/ml (10,000 ppm)	>240
Daunorubicin HCL, 5 mg/ml (5,000 ppm)	>240
Docetaxel, 10 mg/ml (10,000 ppm)	>240
Doxorubicin HCL, 2 mg/ml (2,000 ppm)	>240
Etoposide, 20 mg/ml (20,000 ppm)	>240
Epirubicin HCL, 2 mg/ml (2,000 ppm)	>240
Fludarabine, 25 mg/ml (25,000 ppm)	>240
Fluorouracil, 50mg/ml (50,000ppm)	>240
Gemcitabine, 38mg/ml (38,000ppm)	>240
Idarubicin HCL, 1mg/ml (1,000ppm)	>240
Ifosfamide, 50mg/ml (50,000ppm)	>240
Irinotecan, 20mg/ml (20,000ppm)	>240
Mechlorethamine HCI, 1mg/ml (1,000ppm)	>240
Melphalan, 5mg/ml (5,000ppm)	>240
Methotrexate, 25mg/ml (25,000ppm)	>240
Mitomycin C, 0.5mg/ml (500ppm)	>240
Mitoxantrone HCL, 2mg/ml (2,000ppm)	>240
Oxaliplatin, 5mg/ml (5,000ppm)	>240
Paclitaxel, 6mg/ml (6,000ppm)	>240
Paraplatin, 10mg/ml (10,000ppm)	>240
Retrovir, 10mg/ml (10,000ppm)	>240
Rituximab, 10mg/ml (10,000ppm)	>240
Thio Tepa, 10mg/ml (10,000ppm)	35.6
Topotecan, 1mg/ml (1,000ppm)	>240
Trisenox, 1mg/ml (1,000ppm)	>240

Velcade (Bortezomib), 1mg/ml (1,000ppm)	>240
Vincristine Sulfate (Oncovin), 1mg/ml (1,000ppm)	>240
Vinorelbine, 10 mg/ml (10000ppm)	>240

Fentanyl Citrate	Minimum Breakthrough Detection Time (Minutes)
Fentanyl Citrate Injection (100 mcg/2ml)	>240

*Please note that the following drugs have extremely low permeation times:
Carmustine: 12.9 minutes, Thio Tepa: 35.6 minutes
Warning: Do not use with Carmustine and Thio Tepa.

6. Comparison of Subject Device and Predicate Devices:

The following tables are summaries of the technological characteristics, biocompatibility and testing for the subject Device and predicate devices.
General Comparison Table:

	Subject Device K231643	Predicate Device K200581	Reference Device K221269	Comparison
Trade Name	Biodegradable Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate(Blue)	Biodegradable Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue)	Powder Free Nitrile Examination Glove (Blue) Tested for Use with Chemotherapy Drugs and Fentanyl Citrate	Similar
Product Code	LZA, LZC, OPJ, QDO	LZA, LZC,QDO	LZA, LZC,QDO	Different*
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	21 CFR 880.6250	Same
Class	I	I	I	Same
Indications for Use	Biodegradable Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue) is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. Gloves have been tested for use with chemotherapy drugs and Fentanyl Citrate using ASTM D6978-05(2019)	Biodegradable Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue) is a patient medical exam glove which is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between examiner and patient. It is also tested to be used against chemotherapy drugs and Fentanyl Citrate	The device is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. These gloves were tested for use with chemotherapy drugs and Fentanyl listed on the label.	Same as K200581
Material	Nitrile	Nitrile	Nitrile	Same

510K Summary K231643

Powder or Powder Free	Powder Free	Powder Free	Powder Free	Same
Color	Blue	Blue	Blue	Same
Single use	Single use	Single use	Single use	Same
Chemotherapy Drugs and Fentanyl Citrate Claim	See below comparison table	See below comparison table	See below comparison table	/
Biodegradation Properties	Biodegradable	Biodegradable	/	Same as K200581

** QDO and OPJ, both designated for Medical Gloves with Chemotherapy Labeling Claims - Test For Use With Chemotherapy Drugs, the subject device added the product code OPJ as per requirements but does not raise questions of safety and effectiveness.*

Technological Characteristic Comparison Table:

Technological Characteristics	Subject Device K231643	Predicate Device K200581	Reference Device K221269	Comparison
Physical Dimension				
Length	Minimum 220mm for sizes XS and S, 230mm for size M-XXL	Minimum 220mm for sizes XS and S, 230mm for size M-XXL	Minimum 220mm for sizes XS and S, 230mm for size M-XXL	Same
Palm Width (size) (mm)				
XS	70±10	70±10	70±10	Same
S	80±10	80±10	80±10	Same
M	95±10	95±10	95±10	Same
L	110±10	110±10	110±10	Same
XL	120±10	120±10	120±10	Same
XXL	130±10	130±10	130±10	Same
Thickness(mm)				
Finger	Minimum 0.05	Minimum 0.05	Minimum 0.05	Same
Palm	Minimum 0.05	Minimum 0.05	Minimum 0.05	Same
Physical Property				
Tensile Strength, Before Aging	14MPa, min	14MPa, min	14MPa, min	Same
Ultimate Elongation, Before Aging	500%, min	500%, min	500%, min	Same
Tensile Strength, After Accelerated Aging	14MPa, min	14MPa, min	14MPa, min	Same

Ultimate Elongation, After Accelerated Aging	400%, min	400%, min	400%, min	Same
Watertight (1000ml)	G-I, AQL2.5	G-I, AQL2.5	G-I, AQL2.5	Same
Powder-Content	≤ 2 mg per glove	≤ 2 mg per glove	≤ 2 mg per glove	Same
In vitro Cytotoxicity ISO 10993-5	The test article extract showed potential toxicity to L929 cells.	N/A	The test article extract showed potential toxicity to L929 cells.	Same as K221269
Acute Systemic Toxicity Test ISO 10993-11	Under the conditions of this study, the device showed no evidence of acute systemic toxicity	Under the conditions of this study, the device showed no evidence of acute systemic toxicity	Under the conditions of this study, the device showed no evidence of acute systemic toxicity	Same
Dermal Sensitization ISO 10993-10	Under the conditions of the study, the device is not a sensitizer	Under the conditions of the study, the device is not a sensitizer	Under the conditions of the study, the device is not a sensitizer	Same
Primary Skin Irritation ISO 10993-23	Under the conditions of the study, the device is not an irritant	Under the conditions of the study, the device is not an irritant	Under the conditions of the study, the device is not an irritant	Same

Chemotherapy Permeation and Fentanyl Citrate Comparison Claim:

Tested Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time (Minutes)			Comparison
	Subject Device K231643	Predicate Device K200581	Reference Device K221269	
Azacytidine (Vidaza) 25 mg/ml (25000ppm)	>240	>240	/	Same as K200581
Bleomycin Sulfate 15mg/ml (15000 ppm)	>240	/	>240	Same as K221269
Busulfan 6mg/ml (6,000 ppm)	>240	/	>240	Same as K221269
Carboplatin 10mg/ml (10,000 ppm)	>240	>240	>240	Same
Carmustine (BCNU)3.3 mg/ml (3,300 ppm)	12.9	21.4	11.1	Similar
Chloroquine 50mg/ml (50,000ppm)	>240	/	>240	Same as K221269
Cisplatin 1mg/ml (1,000 ppm)	>240	>240	>240	Same

Cyclophosphamide 20mg/ml (20,000 ppm)	>240	>240	>240	Same
Cyclosporin A 100 mg/ml (100,000 ppm)	>240	/	>240	Same as K221269
Cytarabine HCL, 100 mg/ml (100,000 ppm)	>240	/	>240	Same as K221269
Dacarbazine 10 mg/ml (10,000 ppm)	>240	>240	>240	Same
Daunorubicin HCL, 5 mg/ml (5,000 ppm)	>240	/	>240	Same as K221269
Docetaxel, 10 mg/ml (10,000 ppm)	>240	>240	>240	Same
Doxorubicin HCL, 2 mg/ml (2,000 ppm)	>240	>240	>240	Same
Etoposide, 20 mg/ml (20,000 ppm)	>240	>240	>240	Same
Epirubicin HCL, 2 mg/ml (2,000 ppm)	>240	>240	>240	Same
Fludarabine, 25 mg/ml (25,000 ppm)	>240	/	>240	Same as K221269
Fluorouracil, 50mg/ml (50,000ppm)	>240	>240	>240	Same
Gemcitabine, 38mg/ml (38,000ppm)	>240	>240	>240	Same
Idarubicin HCL, 1mg/ml (1,000ppm)	>240	/	>240	Same as K221269
Ifosfamide, 50mg/ml (50,000ppm)	>240	>240	>240	Same
Irinotecan, 20mg/ml (20,000ppm)	>240	>240	>240	Same
Mechlorethamine HCI, 1mg/ml (1,000ppm)	>240	/	>240	Same as K221269
Melphalan, 5mg/ml (5,000ppm)	>240	/	>240	Same as K221269
Methotrexate, 25mg/ml (25,000ppm)	>240	>240	>240	Same
Mitomycin C, 0.5mg/ml (500ppm)	>240	>240	>240	Same
Mitoxantrone HCL, 2mg/ml (2,000ppm)	>240	>240	>240	Same
Oxaliplatin, 5mg/ml (5,000ppm)	>240	>240	>240	Same
Paclitaxel, 6mg/ml (6,000ppm)	>240	>240	>240	Same
Paraplatin, 10mg/ml (10,000ppm)	>240	/	>240	Same as K221269
Retrovir, 10mg/ml (10,000ppm)	>240	/	>240	Same as K221269
Rituximab, 10mg/ml (10,000ppm)	>240	/	>240	Same as K221269
Thio Tepa, 10mg/ml (10,000ppm)	35.6	67.2	21.6	Similar
Topotecan, 1mg/ml (1,000ppm)	>240	/	>240	Same as K221269
Trisenox, 1mg/ml (1,000ppm)	>240	/	>240	Same as K221269
Velcade (Bortezomib), 1mg/ml (1,000ppm)	>240	/	>240	Same as K221269
Vincristine Sulfate (Oncovin), 1mg/ml (1,000ppm)	>240	>240	>240	Same

Vinorelbine, 10 mg/ml (10000ppm)	>240	>240	/	Same as K200581
Fentanyl Citrate Injection (100 mcg/2ml)	>240	>240	>240	Same

** Chemotherapy drugs and the minimum breakthrough time of subject device will be listed on labeling.*

7. Summary of Non-Clinical Performance Data

Non-clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device met the performance criteria with the following standards:

Methodology	Test Performed	Acceptance Criteria	Results
ASTM D6319- 19	Physical Dimensions Length	Minimum 220mm for sizes XS and S, 230mm for size M-XXL	Pass
ASTM D6319- 19	Physical Dimensions Palm Width	XS: 70±10mm S: 80±10mm M: 95±10mm L:110±10mm XL: 120±10mm XXL: 130±10mm	Pass
ASTM D6319- 19	Physical Dimensions Thickness	Finger: 0.05mm (min) Palm: 0.05mm (min)	Pass
ASTM D6319- 19 ASTM D412-16(2021)	Physical Properties	Tensile Strength (Min14 Mpa) and Elongation (Before Aging 500% and after aging 400%) Min	Pass
ASTM D6319- 19 ASTM D5151-19	Water leak test	AQL 2.5 (ISO 2859-1)	Pass
ASTM D6319- 19 ASTM D6124-06 (2017)	Powder Residue	Max 2mg/glove	Pass
ASTM D6978-05 (2019)	Permeation by Chemotherapy Drugs	Refer the above table in Section 5	Pass
ISO 10993-10 &23:2021	Irritation and Skin Sensitization	Skin sensitization and Skin irritation	Is non-sensitization and Non-irritation
ISO 10993-5:2009	Cytotoxicity	Cytotoxicity reactivity	showed potential toxicity to L929 cells.
ISO 10993-11:2017	Acute systemic toxicity study	Subject showed no adverse biological reaction	no evidence of acute systemic toxicity.
ISO 11737-1:2018	Open box bioburden study	There is no increase in bioburden levels	Pass

- ASTM D6319-19, Standard Specification for Nitrile Examination Gloves for Medical Application.
- ASTM D5151-19, Standard Test Method for Detection of Holes in Medical Gloves.
- ASTM D6124-06 (Reapproved 2017), Standard Test Method for Residual Powder on Medical Gloves
- ASTM D412-16（2021）Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension
- ASTM D6978-05 (Reapproved 2019), Assessment of Resistance of Medical Gloves to Permeation by

Chemotherapy Drugs.

- ISO 10993-10:2021 Biological Evaluation of Medical Devices - Part 10: Tests For Skin Sensitization.
- ISO 10993-23:2021 Biological Evaluation of Medical Devices - Part 10: Tests For Skin Irritation.
- ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity
- ISO 10993-11:2017 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
- ISO 11737-1:2018 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products.

8. Clinical Performance Data

N/A

9. Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.