October 20, 2023

Ansell Healthcare
Carson Delaloye
Senior Administrator Quality
2301 Robb Drive
Reno, Nevada 89523

Re: K231902

Trade/Device Name: GAMMEX PI Hybrid Micro (340002055); GAMMEX PI Hybrid Micro (340002060); GAMMEX PI Hybrid Micro (340002065); GAMMEX PI Hybrid Micro (340002070); GAMMEX PI Hybrid Micro (340002075); GAMMEX PI Hybrid Micro (340002080); GAMMEX PI Hybrid Micro (340002085); GAMMEX PI Hybrid Micro (340002090)
Regulation Number: 21 CFR 878.4460
Regulation Name: Non-Powdered Surgeon's Glove
Regulatory Class: Class I, reserved
Product Code: KGO, OPJ
Dated: September 21, 2023
Received: September 21, 2023

Dear Carson Delaloye:

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.

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,

Bifeng Qian -S

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

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)*
K231902

Device Name
GAMMEX PI Hybrid Micro (340002055); GAMMEX PI Hybrid Micro (340002060); GAMMEX PI Hybrid Micro (340002065); GAMMEX PI Hybrid Micro (340002070); GAMMEX PI Hybrid Micro (340002075); GAMMEX PI Hybrid Micro (340002080); GAMMEX PI Hybrid Micro (340002085); GAMMEX PI Hybrid Micro (340002090)

Indications for Use *(Describe)*
Gammex PI Hybrid Micro Surgical Gloves are sterile, non-pyrogenic, are intended to be worn by operating room personnel to protect a surgical wound from contamination and have a shelf life of 3 years. These gloves were tested for use with Chemotherapy Drugs as per ASTM D6978 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.
Tested chemotherapy drugs are as follows:
Test chemotherapy drug and concentration Minimum breakthrough detection time in minutes
Bleomycin (15.0 mg/ml) >240
Busulfan (6.0 mg/ml) >240
Carboplatin (10.0 mg/ml) >240
Carmustine (3.3 mg/ml) 24.1
Cisplatin (1.0 mg/ml) >240
Cyclophosphamide (20.0 mg/ml) >240
Cytarabine HCl (100.0 mg/ml) >240
Dacarbazine (10.0 mg/ml) >240
Daunorubicin HCl (5.0 mg/ml) >240
Docetaxel (10.0 mg/ml) >240
Doxorubicin HCl (2.0 mg/ml) >240
Epirubicin (2.0 mg/ml) >240
Etoposide (20.0 mg/ml) >240
Fludarabine (25.0 mg/ml) >240
Fluorouracil (50.0 mg/ml) >240
Gemcitabine (38.0 mg/ml) >240
Idarubicin (1.0 mg/ml) >240
Ifosfamide (50.0 mg/ml) >240
Irinotecan (20.0 mg/ml) >240
Mechlorethamine HCI (1.0 mg/ml) >240
Melphalan (5.0mg/ml) >240
Methotrexate (25.0 mg/ml) >240
Mitomycin C (0.5 mg/ml) >240
Mitoxantrone (2.0mg/ml) >240
Oxaliplatin (2.0 mg/ml) >240
Paclitaxel (6.0 mg/ml) >240
Rituximab (10.0 mg/ml) >240
ThioTEPA (10.0 mg/ml) 26.0
Vincristine Sulfate (1.0 mg/ml) >240
Warning: Do not use with Carmustine or ThioTEPA

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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510KSummary

510(k) Number:

K231902

Submitter:

Ansell Healthcare
2301 Robb Drive Reno, NV
89523

Contact Person(s):

Carson Delaloye
Senior Coordinator, Regulatory Affairs
Phone: 530-401-8977
Email: carson.delaloye@ansell.com

Date Prepared

October 16, 2023

Name of Device

Trade Names:	GAMMEX PI Hybrid Micro (340002055); GAMMEX PI Hybrid Micro (340002060); GAMMEX PI Hybrid Micro (340002065); GAMMEX PI Hybrid Micro (340002070); GAMMEX PI Hybrid Micro (340002075); GAMMEX PI Hybrid Micro (340002080); GAMMEX PI Hybrid Micro (340002085); GAMMEX PI Hybrid Micro (340002090)
Common Name:	Surgeon's Gloves
Classification Name:	Non-Powdered Surgeon's Glove
Classification Regulation:	21 CFR 878.4460
Device Class:	I
Product Code:	KGO, OPJ
Classification Panel:	General and Plastic Surgery

Legally Marketed Predicate Device

K182948

Trade Name:	Gammex PI Hybrid Surgical Gloves Tested for Use with Chemotherapy Drugs
Common Name:	Surgeon's Gloves
Classification Name:	Non-Powdered Surgeon's Glove

Classification Regulation:	21 CFR 878.4460
Device Class:	I
Product Code:	KGO
Classification Panel:	General and Plastic Surgery

Device Description

Gammex PI Hybrid Micro Surgical Gloves are sterile and disposable devices. The gloves are made of a synthetic rubber polyisoprene and neoprene blend. Ansell has performed independent laboratory testing to support use with Chemotherapy Drugs and Non-Pyrogenic claims. The glove has a shelf life of 3 years, is brown in color and comes in the following sizes: 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0. Each size is assigned with a model number.

Indication for Use Statement

Gammex PI Hybrid Micro Surgical Gloves are sterile, non-pyrogenic, are intended to be worn by operating room personnel to protect a surgical wound from contamination and have a shelf life of 3 years. These gloves were tested for use with Chemotherapy Drugs as per ASTM D6978 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Tested chemotherapy drugs are as follows:

Test chemotherapy drug and concentration	Minimum breakthrough detection time in minutes
Bleomycin (15.0 mg/ml)	>240
Busulfan (6.0 mg/ml)	>240
Carboplatin (10.0 mg/ml)	>240
Carmustine (3.3 mg/ml)	24.1
Cisplatin (1.0 mg/ml)	>240
Cyclophosphamide (20.0 mg/ml)	>240
Cytarabine HCl (100.0 mg/ml)	>240
Dacarbazine (10.0 mg/ml)	>240
Daunorubicin HCl (5.0 mg/ml)	>240
Docetaxel (10.0 mg/ml)	>240
Doxorubicin HCl (2.0 mg/ml)	>240
Epirubicin (2.0 mg/ml)	>240
Etoposide (20.0 mg/ml)	>240
Fludarabine (25.0 mg/ml)	>240
Fluorouracil (50.0 mg/ml)	>240
Gemcitabine (38.0 mg/ml)	>240
Idarubicin (1.0 mg/ml)	>240
Ifosfamide (50.0 mg/ml)	>240
Irinotecan (20.0 mg/ml)	>240
Mechlorethamine HCl (1.0 mg/ml)	>240
Melphalan (5.0mg/ml)	>240
Methotrexate (25.0 mg/ml)	>240

Mitomycin C (0.5 mg/ml)	>240
Mitoxantrone (2.0mg/ml)	>240
Oxaliplatin (2.0 mg/ml)	>240
Paclitaxel (6.0 mg/ml)	>240
Rituximab (10.0 mg/ml)	>240
ThioTEPA (10.0 mg/ml)	26.0
Vincristine Sulfate (1.0 mg/ml)	>240

Warning: Do not use with Carmustine or ThioTEPA

Technological Characteristics:

Technological Characteristics Comparison Table for Predicate Device

	Predicate Device	**Proposed Subject Device**	**Comparison**
Trade name	Gammex PI Hybrid Surgical Gloves Tested for Use with Chemotherapy Drugs	GAMMEX PI Hybrid Micro (340002055); GAMMEX PI Hybrid Micro (340002060); GAMMEX PI Hybrid Micro (340002065); GAMMEX PI Hybrid Micro (340002070); GAMMEX PI Hybrid Micro (340002075); GAMMEX PI Hybrid Micro (340002080); GAMMEX PI Hybrid Micro (340002085); GAMMEX PI Hybrid Micro (340002090)	Different – Trade Name o The names are different to indicate which of the devices is the smaller version. This does not affect safety or efficacy as the difference is to inform the end user.
510k Number	K182948	K231902	Different -New 510(k)
Product Owner	Ansell Healthcare	Ansell Healthcare	Same
Product Code	KGO	KGO, OPJ	Different –OPJ product code added for chemo
Regulation Number	21 CFR 878.4460	21 CFR 878.4460	Same
Regulatory Class	I	I	Same
Regulation Name	Non-powdered Surgeon's Gloves	Non-powdered Surgeon's glove	Same
Indications for Use	Gammex PI Hybrid Surgical Gloves are intended to be worn by operating room personnel to protect a surgical wound from contamination. These gloves were tested for use with Chemotherapy Drugs as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs. Tested chemotherapy drugs are as follows: Test Chemotherapy drug & Concentration Minimum Breakthrough Detection Time in Minutes Bleomycin sulfate (15.0 mg/ml) >240	Gammex PI Hybrid Micro Surgical Gloves are sterile, non-pyrogenic, are intended to be worn by operating room personnel to protect a surgical wound from contamination and have a shelf life of 3 years. These gloves were tested for use with Chemotherapy Drugs as per ASTM D6978 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs. Tested chemotherapy drugs are as follows: Test Chemotherapy drug & concentration Minimum Breakthrough detection time in minutes Bleomycin sulfate (15.0 mg/ml) >240 Busulfan (6.0 mg/ml) >240	Different Itemized List of Differences Between Predicate and Proposed: • Indications for Use o The indications for use differ as the proposed device carries non-pyrogenic claims. The permeation times also differ for Carmustine and ThioTEPA.

	Busulfan (6.0 mg/ml) >240 Carboplatin (10.0 mg/ml) >240 Carmustine (3.3 mg/ml) 23.6 Cisplatin (1.0 mg/ml) >240 Cyclophosphamide (20.0 mg/ml) >240 Cytarabine (100.0 mg/ml) >240 Dacarbazine (10 mg/ml) >240 Daunorubicin (5.0 mg/ml) >240 Docetaxel (10.0 mg/ml) >240 Doxorubicin Hydrochloride (2.0 mg/ml) >240 Epirubicin (2.0 mg/ml) >240 Etoposide (20.0 mg/ml) >240 Fludarabine (25.0 mg/ml) >240 Fluorouracil(50.0 mg/ml) >240 Gemcitabine (Gemzar) (38.0 mg/ml) >240 Idarubicin (1.0 mg/ml) >240 Ifosfamide (50.0 mg/ml) >240 Irinotecan (20.0 mg/ml) >240 Mechlorethamine HCl(1.0 mg/ml) >240 Melphalan (5.0 mg/ml) >240 Methotrexate (25.0 mg/ml) >240 Mitomycin C (0.5 mg/ml) >240 Mitoxantrone (2.0 mg/ml) >240 Oxaliplatin (2.0 mg/ml) >240 Paclitaxel (Taxol) (6.0 mg/ml) >240 Rituximab (10.0 mg/ml) >240 ThioTEPA (10.0 mg/ml) 36.1 Vincristine Sulfate(1.0 mg/ml) >240	Carboplatin (10.0 mg/ml) >240 Carmustine (3.3 mg/ml) 24.1 Cisplatin (1.0 mg/ml) >240 Cyclophosphamide (20.0 mg/ml) >240 Cytarbine (100.0 mg/ml) >240 Dacarbazine (10 mg/ml) >240 Daunorubicin (5.0 mg/ml) >240 Docetaxel (10.0 mg/ml) >240 Doxorubicin Hydrochloride (2.0 mg/ml) >240 Epirubicin (2.0 mg/ml) >240 Etoposide (20.0 mg/ml) >240 Fludarabine (25.0 mg/ml) >240 Fluorouracil (50.0 mg/ml) >240 Gemcitabine (Gemzar) (38.0 mg/ml) >240 Idarubicin (1.0 mg/ml) >240 Ifosfamide (50.0 mg/ml) >240 Irinotecan (20.0 mg/ml) >240 Mechlorethamine HCl (1.0 mg/ml) >240 Melphalan (5.0 mg/ml) >240 Methotrexate (25.0 mg/ml >240 Mitomycin C (0.5 mg/ml) >240 Mitoxantrone (2.0 mg/ml) >240 Oxaliplatin (2.0 mg/ml) >240 Paclitaxel (Taxol) (6.0 mg/ml) >240 Rituximab (10.0 mg/ml) >240 ThioTEPA (10.0 mg/ml) 26.0 Vincristine Sulfate (1.0 mg/ml) >240 Warning: Do not use with Carmustine or ThioTEPA	
Material Composition	Synthetic polyisoprene rubber	Synthetic polyisoprene rubber	Same
Coating	Polymer Coating	Polymer Coating	Same
Design	Single use	Single use	Same
	Powder-free	Powder-free	Same
	Hand Specific	Hand Specific	Same
	Beaded cuff	Beaded cuff	Same
Color	Natural	Brown	Different – Changed Color
Labeling	Surgeon's Gloves	Surgeon's Gloves	Same
Shelf Life	3 Years	3 Years	Same
Performance a. **Dimensions**	Meets ASTM D3577-19 (2015) requirements	Meets ASTM D3577-19 requirements	Same
b. **Physical Properties**	Meets ASTM D3577-19 (2015) requirements	Meets ASTM D3577-19 requirements	Same
c. **Freedom from holes**	Meets ASTM D3577-19 (2015) AQL Meets CFR 800.20 Requirements	Meets ASTM D3577-19 (2015) AQL Meets CFR 800.20 Requirements	Same
d. **Powder Residual**	Meet applicable definition for powder free per ASTM D3577-19; ≤ 2mg per glove	Meet applicable definition for powder free per ASTM D3577-19; ≤ 2mg per glove	Same
e. **Sterility**	Sterile	Sterile	Same
Bio-compatibility Skin Irritation	Passes Primary Skin Irritation test per ISO 10993-10, Biological Evaluation of medical	Passes Primary Skin Irritation test per ISO 10993-10, Biological Evaluation of medical devices, Part 10: Test for irritation and skin sensitization	Same

	devices, Part 10: Test for irritation and skin sensitization		
Bio-compatibility Sensitization	Passes Dermal Sensitization test per ISO 10993-10, Biological Evaluation of medical devices, Part 10: Test for irritation and skin sensitization	Passes Dermal Sensitization test per ISO 10993-10, Biological Evaluation of medical devices, Part 10: Test for irritation and skin sensitization	Same
Bio-compatibility Acute Systemic Toxicity	Passes Acute Systemic Toxicity Test per ISO 10993-11, Biological Evaluation of medical devices, Part 11: Test for systemic toxicity	Passes Acute Systemic Toxicity Test per ISO 10993-11, Biological Evaluation of medical devices, Part 11: Test for systemic toxicity	Same
Bio-compatibility Cytotoxicity	Under the conditions of the study, the device extract was found to be cytotoxic and therefore the device extracts were evaluated by ISO 10993-11 - Test for systemic toxicity. From the Acute Systemic Toxicity device extracts, the device extracts did not elicit a systemic response in the animal model	Under the conditions of the study, the device extract was found to be cytotoxic and therefore the device extracts were evaluated by ISO 10993-11 - Test for systemic toxicity. From the Acute Systemic Toxicity device extracts, the device extracts did not elicit a systemic response in the animal model	Same
Non-pyrogenic	Not reported	Passes Material Mediated Pyrogenicity Test per USP <151>. Under the conditions of the study, non-pyrogenic. Less than 20.0 EU/device. Under the conditions of the study, low endotoxin levels.	Different
Sterilization Method	Gamma Irradiation	Gamma Irradiation	Same
Sterilization Information	Meets ANSI/AAMI/ISO 11137- 1:2006 requirement of 10^{-6} SAL.	Meets ANSI/AAMI/ISO 11137-1:2006 requirement of 10^{-6} SAL.	Same
Prescription or Over The Counter	Over the Counter	Over the Counter	Same

Itemized List of Differences Between Predicate and Proposed:

- Trade Name
  The names are different to indicate which of the devices is the smaller version. This does not affect safety or efficacy as the difference is to inform the end user.
- Indications For Use
  The indications for use differ as the proposed device carries non-pyrogenic claims. The permeation times also differ for Carmustine and ThioTEPA.
- Color
  The color is listed as different for the devices. Brown pigmentation was added to the Proposed Subject device.
- Non-pyrogenic
  The proposed device has demonstrated low endotoxin levels and did not elicit a pyrogenic response in testing. Testing was not reported for the predicate device.

Non-Clinical Testing

Gammex® PI Plus Glove-in-Glove™ System Tested for Use with Chemotherapy Drugs has the following technological characteristics as compared to ASTM or equivalent standards:

Results	Title of Test	Purpose of Test	Acceptance Criteria
PASS	ASTM D3767-03	Dimensions	Acceptance criteria in accordance with ASTM D3577-19: *Standard Specification for Rubber Surgical Gloves*
PASS	ASTM D3577-19	Physical Properties	Acceptance criteria for tensile strength, ultimate elongation and stress at 500% elongation before and after accelerated aging for synthetic surgical gloves per ASTM D3577-19: *Standard Specification for Rubber Surgical Gloves*
PASS	ASTM D5151-19	Freedom from holes	Acceptance criteria in accordance with ASTM D3577-19: *Standard Specification for Rubber Surgical Gloves* with AQL requirements of 1.5
PASS	ASTM D6124	Powder-Free	Meets applicable acceptance criteria for powder free ≤ 2mg per glove per ASTM D3577-19: *Standard Specification for Rubber Surgical Gloves*
PASS	ANSI/AAMI/ ISO 11137-1:2006	Sterility	Meets acceptance criteria requirement of 10^{-6} SAL per ISO 11137-1: *Sterilization for Health Care Products – Radiation – Part 1: Requirements for Development, Validation and Routine Control of A Sterilization Process For Medical Devices*
PASS	ASTM D6978- 05(2019)	Chemotherapy Drug Permeation Test	Acceptance Criteria in accordance with ASTM D6978-05(2019): *Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.* *Please note that the following drugs have extremely low permeation times: Carmustine (24.1 min) and Thiotepa (26.0 min)
FAIL	ISO 10993-5	ISO *in vitro* Cytotoxicity Study	Surfaces at undiluted were found to be cytotoxic (grade 4) to L-929 cells and non-cytotoxic with grade 0 at 1:2, 1:4, 1:8, :16, 1:32 and 1;64 dilutions. Acceptance criteria in accordance with ISO 10993-5: *Biological Evaluation of Medical Devices, Part 5: Tests for In Vitro Cytotoxicity, 2009.*
PASS	ISO 10993-10:2010	ISO Skin Irritation Study	Passes Primary Skin Irritation test per ISO 10993-10, *Biological Evaluation Of Medical Devices, Part 10: Test for Irritation and Skin Sensitization*. Under the conditions of the study, not an irritant.
PASS	ISO 10993-10:2010	ISO Maximization Sensitization Study	Passes Dermal Sensitization test per ISO 10993-10, *Biological Evaluation of medical devices, Part 10: Test for Irritation and Skin Sensitization*. Under the conditions of the study, not a sensitizer
PASS	ISO 10993-11:2017	ISO Acute Systemic Toxicity Study – ISO 10993-11:2017	Passes Acute Systemic Toxicity Test per ISO 10993-11, *Biological Evaluation of medical devices, Part 11: Test for Systemic Toxicity*. Under the conditions of the study, there was no mortality or evidence of acute systemic toxicity
PASS	USP <151>	Material Mediated Pyrogenicity Study – USP <151>	Passes Material Mediated Pyrogenicity Test per USP <151>. Under the conditions of the study, non-pyrogenic.
PASS	Endotoxin Study	Demonstrate low endotoxin levels	Less than 20.0 EU/device

Clinical Studies

A clinical study was not conducted on the subject device.

Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device, GAMMEX PI Hybrid Micro, is as safe, as effective, and performs as well as or better than the legally marketed device K182948.