May 22, 2020

AngioDynamics, Inc.
Vidyalakshmi Jayaraman
Specialist, Global Regulatory Affairs
26 Forest Street
Marlborough, Massachusetts 01752

Re: K190559
Trade/Device Name: SmartPort+ and SmartPort Plastic Implantable Ports
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: Class II
Product Code: LJT
Dated: March 20, 2020
Received: March 23, 2020

Dear Vidyalakshmi Jayaraman:

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,

Sapana Patel -S

for Tina Kiang, Ph.D.
Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190559

Device Name
SmartPort+ and SmartPort Plastic Implantable Ports

Indications for Use *(Describe)*
The ports are indicated for patients who require long-term access to the central venous system for blood specimen withdrawal and administration of fluids including but not limited to hydration fluids, chemotherapy, analgesics, nutritional therapy and blood products, as well as the administration and adequate removal of nuclear medicine.

When used with power injectable needles, the ports are indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 mL/s with 19G or 20G non-coring power injectable needles or 2 mL/s with a 22G non-coring power injectable needle.

Needle Size (G), non-coring power injectable	Catheter Size (F)	Maximum Recommended Flow Rate Setting (mL/s)	Maximum Recommended Pressure Setting (psi)
19/20	5,6 and 8	5	300
22	5,6 and 8	2	300

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 - K190559

Date Prepared: May 22, 2020

A.SPONSOR

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C. DEVICE NAME

Trade Name:	SmartPort+ and SmartPort Plastic Implantable Ports
Common/Usual Name:	Implanted Port Catheter, Subcutaneous
Classification Name:	Implanted, Intravascular Infusion Port and Catheter
Classification Panel:	General Hospital
Product code:	LJT
Regulation number:	880.5965

D.PREDICATE DEVICE(S)

1. 510(k) Number	K101017
Trade Name:	AngioDynamics Inc. Smart Port CT Series Port Access Systems
Common/Usual Name:	Implanted Port Catheter, Subcutaneous
Classification Name:	Implanted, Intravascular Infusion Port and Catheter
Classification Panel:	General Hospital
Product code:	LJT
Regulation number:	880.5965

2. 510(k) Number	K131694
Trade Name:	NMI Port II
Common/Usual Name:	Implanted Port Catheter, Subcutaneous
Classification Name:	Implanted, Intravascular Infusion Port and Catheter
Classification Panel:	General Hospital
Product code:	LJT
Regulation number:	880.5965

E. DEVICE DESCRIPTION

The SmartPort+ device with ENDEXO and Vortex Technology and the SmartPort Plastic device with Vortex Technology are implantable venous access devices designed for repeated access to the vascular system. The SmartPort+ and SmartPort Plastic devices are subcutaneous implant devices with one reservoir. The ports are accessed using a Huber needle which is passed through the skin and into the self-sealing silicone septum covering the reservoir. When used with power injectable needles, the port can be used for power injection of contrast media and contrast enhanced computed tomography (CECT).

Available in plastic and titanium port bodies, the SmartPort+ device has standard, low profile, and mini Titanium port configurations and low-profile Plastic port configurations. The ports are offered with a 5F, 6F or 8F single lumen BioFlo catheter. The BioFlo catheter with ENDEXO technology is present in the previously cleared NMI Port II (K131694) for improved resistance to thrombus accumulation and/or formation on the catheter. The outlet of the vortex port chamber is set at a tangent rather than perpendicularly.

The SmartPort Plastic device is offered in a low-profile Plastic port body configuration with a 6F or 8F single lumen polyurethane catheter. Both the BioFlo and polyurethane catheters are radiopaque.

When used with power injectable needles, the ports are indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate setting is 5 mL/s with 19G or 20G non-coring power injectable needles or 2 mL/s with a 22G non-coring power injectable needle.

The ports are available with either silicone filled or non-filled suture fixation holes. If desired, the suture fixation holes can be used to anchor the port to the subcutaneous tissue. All port configurations have a radiopaque identifier (CT mark) as a power injectable port. The radiopaque catheter is marked at every centimeter and can be cut to the desired length.

The ports are packaged with procedural accessories in a kit to the end user

F.INTENDED USE/INDICATIONS FOR USE

The ports are indicated for patients who require long-term access to the central venous system for blood specimen withdrawal and administration of fluids including but not limited to hydration fluids, chemotherapy, analgesics, nutritional therapy and blood products, as well as the administration and adequate removal of nuclear medicine.

When used with power injectable needles, the ports are indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 mL/s with 19G or 20G non-coring power injectable needles or 2 mL/s with a 22G non-coring power injectable needle.

Needle Size (G), non-coring power injectable	Catheter Size (F)	Maximum Recommended Flow Rate Setting (mL/s)	Maximum Recommended Pressure Setting (psi)
19/20	5,6, and 8	5	300
22	5,6, and 8	2	300

G.SUMMARY OF SIMILARITIES AND DIFFERENCES IN TECHNOLOGICAL CHARACTERISTICS AND PERFORMANCE

The proposed devices have similar materials, design and components as the predicate devices. Both the proposed devices and predicate ports are, in brief, intended for patients who require long-term access to the central venous system for administration of fluids including but not limited to hydration fluids, chemotherapy, analgesics, nutritional therapy and blood products; available in single lumen configurations and plastic or titanium port bodies; rated for maximum power injector settings up to 300 psi with maximum power injection flow rate up to 5 ml/second based on model; and available kitted with a variety of procedural accessories.

The table below described key similarities and differences between predicate and proposed ports.

<table>
<tr><th>Device Characteristic</th><th>SmartPort+ and SmartPort Plastic ports
510(k) number K190559</th><th>Predicate
Smart Port CT Series
Port Access Systems
510(k) number K101017</th><th>Predicate
NMI Port II
510(k) number
K131694</th></tr>
<tr><td>Indication for use</td><td>SmartPort+ and SmartPort Plastic ports are indicated for patients who require long-term access to the central venous system for blood specimen withdrawal and administration of fluids including but not limited to hydration fluids, chemotherapy, analgesics, nutritional therapy and blood products, as well as the administration and adequate removal of nuclear medicine.

When used with power injectable needles, the ports are indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 mL/s with 19G or 20G non-coring power injectable needles or 2 mL/s with a 22G non-coring power injectable needle.

<table>
<tr><th>Needle Size (G), non-coring power injectable</th><th>Catheter Size (F)</th><th>Maximum Recommended Flow Rate Setting (mL/s)</th><th>Maximum Recommended Pressure Setting (psi)</th></tr>
<tr><td>19/20</td><td>5,6, and 8</td><td>5</td><td>300</td></tr>
<tr><td>22</td><td>5,6, and 8</td><td>2</td><td>300</td></tr>
</table>
</td><td>The Smart Port CT Port Access System is indicated for any patient requiring repeated access of the vasculature system, for delivery of medications, nutritional supplementation, fluids, blood, blood products, and sampling of blood. When used with non-Y-site LifeGuard Safety infusion sets in 20 Ga or 19 Ga sizes, the Smart Port CT Access System is indicated for power injection of contrast media. For power injection of contrast media, at a maximum of 300 psi, the maximum recommended infusion rate is 5 mL/s.</td><td>NMI Port II is indicated for patients who require long-term access to the central venous system for administration of fluids including but not limited to hydration fluids, chemotherapy, analgesics, nutritional therapy and blood products. The device is also indicated for blood specimen withdrawal.

When used with a power injectable needle, the port is indicated for power injection of contrast media. The maximum recommended infusion rate at a maximum of 300 psi, is 5 mL/s with a 19G or 20G non-coring power injectable needle or 2 mL/s with a 22G non-coring power injectable needle.</td></tr>
<tr><td>Intended use</td><td>Power injectable ports will be implanted in standard hospital/clinical/radiology suites. During use, the ports are implanted, and will reside in a subcutaneous environment and the catheter will reside in the patient's venous system.

Ports are intended to interact with Huber needles, infusion sets, introducers, guidewires, dilators, and sheaths during implantation. During use, the ports may be subjected to fluoroscopy, CT scout and x-ray imaging. The ports are designed to be used with power injection equipment.

During the implant life, the ports may be subjected up to 1,500 sticks with a 22G needle or 1000 sticks with a 19G or 20G needle.

Puncture Life and Septum Coring tests were done to demonstrate puncture life.</td><td>Same as proposed ports with the exception of puncture limits. The Standard port may be subjected up to 1,000 sticks with a 20G or 22G needle or 500 sticks with a 19G needle. The Mini and Low-Profile ports may be subjected up to 300 sticks with a 19G/20G/22G needle.</td><td>Same as proposed ports with the exception of puncture limits. The ports may be subjected up to 1,334 sticks with a 22G needle or 667 sticks with a 19G or 20G needle.</td></tr>
</table>

Device Characteristic	SmartPort+ and SmartPort Plastic ports 510(k) number K190559	Predicate Smart Port CT Series Port Access Systems 510(k) number K101017	Predicate NMI Port II 510(k) number K131694
Catheter Shaft Material	SmartPort+: Radiopaque Carbothane 85A with 30% Barium Sulfate, 2% Endexo and 0.2% teal colorant SmartPort Plastic: Carbothane 85A 30% Barium Sulfate	Carbothane PC-3585A-B40 and Silicone	Radiopaque Carbothane 85A with 30% Barium Sulfate, 2% Endexo and 0.2% teal colorant
Catheter Priming Volume (ml/10 cm length)	8F - 0.21 6F - 0.13 5F - 0.11	6.6F – 0.16 7.5F - 0.15 8F – 0.18 9.6 F – 0.19	8 F - 0.21 6 F - 0.14
Catheter Shaft Number of Lumens	Single Lumen (SL)	Single Lumen (SL)	Single Lumen (SL)
Catheter Lumen Size ID (mm)	8F - 1.57 6F - 1.27 5F - 1.07	6.6F – 1.42 7.5F - 1.37 8F – 1.52 9.6 F – 1.57	8 F - 1.57 6 F - 1.27
Catheter French Size	SmartPort+: 8F, 6F, 5F SmartPort Plastic: 8F, 6F	6.6F, 7.5F, 8F, 9.6F	8F, 6F
Catheter Length (cm)	63	55, 66	63
Port Body Material	SmartPort+: Titanium, Plastic SmartPort Plastic: Plastic	Titanium	Titanium, Plastic
Maximum Port Base Diameter (mm)	28.6	28.6	25.4
Port Height (mm)	Standard Titanium -13.0 Low Profile Titanium – 11.5 Mini Titanium – 10.8 Low Profile Plastic – 12.1	Standard Titanium -13.0 Low Profile Titanium – 11.5 Mini Titanium – 10.8	Titanium - 11.0 Plastic - 13.3
Port Weight (g)	Standard Titanium ≤ 13 Low Profile Titanium ≤ 10 Mini Titanium ≤ 8 Low Profile Plastic ≤ 5	Standard Titanium ≤ 13 Low Profile Titanium ≤ 10 Mini Titanium ≤ 8	Titanium - 12 Plastic - 6
Port Septum Diameter (mm)	Standard Titanium – 11.9 Low Profile Titanium – 10.2 Mini Titanium - 10.2 Low Profile Plastic – 12.7	Standard Titanium – 11.9 Low Profile Titanium – 10.2 Mini Titanium - 10.2	13

Device Characteristic	SmartPort+ and SmartPort Plastic ports 510(k) number K190559	Predicate Smart Port CT Series Port Access Systems 510(k) number K101017	Predicate NMI Port II 510(k) number K131694
Port Internal Volume (mL)	Less than 1 mL	Less than 1 mL	Less than 1 mL
Port Septum Material	Mini /Low Profile Titanium - NUSIL SILICONE MED-4750 Standard Titanium - NUSIL SILICONE MED-4840 Low Profile Plastic - NUSIL SILICONE MED-4850	NUSIL SILICONE MED-4750	Silopren LSR 4050 Silicone
Maximum pressure of power injectors' setting	300 psi	300 psi	300 psi
Maximum power injection flowrate	5F,6F,8F catheter with 19/20 G needle = 5 mL/sec 5F,6F,8F catheter with 22 G needle = 2 mL/sec	All French sizes with 19/20 G needle = 5 mL/sec	6F,8F catheter with 19/20 G needle = 5 mL/sec 6F,8F catheter with 22 G needle = 2 mL/sec
Attachment Feature (catheter to port)	Plastic and Titanium collars	Titanium collar Silicone collar (blue boot)	Snap Lock connector
PASV Valve Technology	No	No	Yes (valved versions offered)
Incremental markings	Every 1 cm	Every 1 cm	Every 1 cm
MR Conditional	Yes	Yes	Yes

The substantial equivalence discussion table below compares key features of the predicate and subject devices.

Feature	Summary of comparison
Are the predicate devices legally marketed?	Yes, the predicates Smart Port CT Series Port Access System and the predicate, NMI Port II, have been cleared by the FDA 510(k) pathway. Their 510(k) numbers are K101017 and K131694 respectively.
Do the proposed devices have the same intended use as the predicates?	Yes, the proposed and predicate devices are subcutaneous implanted intravascular infusion ports that allow for repeated access to the vascular system for the infusion of fluids and medications and the sampling of blood per 21 CFR 880.5965. The proposed devices have the same intended use as their predicates. They are indicated for patients who require long-term access to the central venous system for blood specimen withdrawal and administration of fluids including but not limited to hydration fluids, chemotherapy, analgesics, nutritional therapy and blood products. When used with power

	injectable needles, the port is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 mL/s with 19G or 20G non-coring power injectable needles or 2 mL/s with a 22G non-coring power injectable needle. The additional indications for use for the proposed ports are that they can be used to administer nuclear medicine. Necessary testing to support this additional indication was completed - all port assemblies tested passed tensile and burst requirements following exposure and flushing of F-flurodeoxyglucose(FDG) and F-Sodium Fluoride (NaF) contrast solutions.
Do the proposed devices have the same technological characteristics as their predicates?	No, though the proposed devices have similar technological features as the predicate devices there are slight differences. 1. **Port design and material:** The proposed ports have the same port reservoir design as the predicate Smart Port CT series (VORTEX technology, K101017). The predicate Smart Port CT series K101017 port body is available only in titanium. The predicate NMI Port II K131694 port bodies are available in titanium and plastic. The proposed SmartPort+ port bodies will be available in Titanium and Plastic, with standard, low profile and mini configurations for Titanium ports and only low profile for Plastic ports. The proposed SmartPort Plastic will be available in a low-profile Plastic port body. 2. **Catheter size:** The predicate Smart Port CT series has 6.6F. 7.5F, 8F and 9.6F catheter sizes. The predicate NMI Port II has 6F and 8F catheter sizes. The proposed SmartPort+ ports will have 8F, 6F and 5F catheter sizes. The addition of a 5F size catheter is due to clinical feedback for the need for a catheter this size. The proposed SmartPort Plastic will have 8F and 6F catheter sizes.

	3. **Catheter material:** The proposed SmartPort+ port will have a BioFlo catheter made of Carbothane containing barium sulfate and ENDEXO. The predicate NMI Port II also includes the BioFlo catheter with Endexo. The proposed SmartPort Plastic port will have a Carbothane catheter. The predicate Smart Port CT series also contains a Carbothane catheter. 4. **Port septum material:** Both proposed ports and the predicates have port septum made of silicone. The types of silicone used in proposed ports are different from that in the predicate devices. Predicate Smart Port CT series has NUSIL SILICONE MED-4750 and predicate NMI Port II has Silopren LSR 4050 Silicone. In the proposed ports, the Mini and Low-Profile Titanium ports have NUSIL SILICONE MED-4750, the Standard Titanium ports have NUSIL SILICONE MED-4840 and the Low-Profile plastic ports have NUSIL SILICONE MED-4850. 5. **MR Conditional:** Both proposed ports and the predicates are MR conditional. 6. **Pressure for power injector setting**: Both proposed ports and the predicates are recommended to be used at a maximum of 300 psi for power injection. 7. **Internal port volume**: Both proposed ports and predicates have an internal port volume of less than 1 mL.
Do the different technological characteristics of the devices raise different questions of safety and effectiveness?	No, the proposed devices and the predicate devices use similar technology for access to the central venous system. All port catheters address questions of biocompatibility and functional performance characteristics. The new characteristics of the proposed devices compared to the predicate devices do not raise new types of safety or effectiveness questions.
Are the proposed scientific methods to evaluate the effect of new/different characteristics in proposed devices on their safety & effectiveness acceptable?	Yes, the performance evaluation of the proposed ports included testing based on FDA Guidance documents and Recognized Standards. This included the FDA Guidance on Premarket Notifications for Implanted Infusion Ports, October 1990. Please refer to section Non-Clinical Performance Testing in this summary for performance standards.

Does the evaluated performance data demonstrate substantial equivalence?	Yes, the data summarized in the 510(k) demonstrate the substantial equivalence of the proposed ports to their predicate devices.

The following table lists the kit accessories included in the predicate and proposed port kits. The proposed ports are packaged with procedural accessories that are either legally marked pre-amendment devices or have been found to be substantially equivalent through the pre-market notification process. The accessories are identical to the accessories provided with the predicate devices.

Predicate Smart Port CT	Predicate NMI Port II	Proposed SmartPort+ and Plastic ports
18 G Introducer Needle 22 G Non-coring Needle PTFE Introducer, 7 Fr x 14 cm Guidewire, 0.035 in x 50 cm LifeGuard Safety Infusion Set, 20 G x 1 in Tunneler Two 10 cc Syringes Blunt Needle Vein Pick	18 G Introducer Needle 0.038 in Guidewire (J-tipped) Peelable Sheath Introducer (Valved or Non-Valved) 17 G Blunt Needle 12 mL Syringe (slip lock) 12 mL Syringe (luer lock) 22 G Huber Needle (straight) 22 G Huber Needle (90 degrees) Tunneler	18 G Introducer Needle 0.038 in Guidewire (J-tipped) Peelable Sheath Introducer (Valved or Non-Valved) 17 G Blunt Needle 12 mL Syringe (slip lock) 12 mL Syringe (luer lock) 22 G Huber Needle (straight) 22 G Huber Needle (90 degrees) Malleable Tunneler (metal) Vein Pick

Non-Clinical Performance Testing

H.Performance Data

The performance evaluation of the SmartPort+ and SmartPort Plastic devices included testing conducting in accordance with the following FDA guidance documents and international standards:

- FDA's "Guidance on 510(k) Submissions for Implanted Infusion Ports dated October 1990.
- EN ISO 10555-1:2013, Intravascular catheters – Sterile and single-use catheters – Part 1: General requirements
- EN ISO 10555-3:2013, Intravascular catheters – Sterile and single-use catheters – Part 3: Central Venous Catheters
- EN ISO 10555-6:2015, Intravascular catheters – Sterile and single-use catheters – Part 6: Subcutaneous Implanted Ports

The proposed ports successfully passed relevant testing per the above Guidance, standards, and pre-established acceptance criteria and internal product specification requirements, including:

- Multiple Power Injections
- Port Septum Testing
- Chemical / Vesicant Compatibility
- Nuclear Medicine Compatibility

- Off-Axial Connection
- Power Injection Flow Rate
- Assembly Leak Strength
- Static Burst Strength
- Port Maximum Operating Pressure, Dynamic
- Catheter Kink Resistance
- Catheter Flex Life Strength
- Catheter Freedom from Leakage
- Catheter Burst Strength
- Catheter Peak Tensile Force
- Catheter Radiopacity
- Catheter Distance Marking
- Catheter Print Integrity
- Catheter Tip Dimensions
- Aspiration Strength – Open Ended
- Aspiration Strength – Closed Ended
- Tunneler to Catheter Compatibility
- 17G Blunt Needle to Catheter Compatibility
- Guidewire to Catheter Compatibility
- Introducer to Catheter Compatibility
- Gravity Flow Rate
- Distribution Simulation
- Surface Finish
- Hyperbaric Chamber Environment

I.Biocompatibility

Biocompatibility testing for the proposed SmartPort+ and SmartPort Plastic ports was performed in accordance with the FDA Guidance document "Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process".

The following tests were performed on ports which were Ethylene Oxide (EtO) sterilized,

- Cytotoxicity
- Sensitization
- Intracutaneous Irritation
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- Subacute Toxicity
- Subchronic Toxicity
- Genotoxicity (Ames Assay, In Vitro Mouse Lymphoma, In Vivo Mouse Micronucleus)
- Implantation (Intramuscular)
- Implantation (Subcutaneous)
- Hemocompatibility (Hemolysis Direct Contact and Extract method, Partial Thromboplastic Time, In-Vitro Hemocompatibility, Complement Activation)
- Carcinogenicity - this was completed with a combination of an assessment of the raw materials and manufacturing process to determine the risk of introduction of carcinogenic and genotoxic materials.

J.Sterilization

The sterilization validation process conforms to the following standard: AAMI/ANSI/ISO 11135:2014 Sterilization of health care products- Ethylene oxide-Requirements for development, validation and routine control of a sterilization process for medical devices. The sterility assurance level (SAL) for the proposed device is 1×10^{-6}.

K.Conclusion

Based on intended use, technology/principle of operation, materials, and performance testing, the subject proposed devices are substantially equivalent when compared to the predicates. The test data supports that subject proposed devices is substantially equivalent to the legally marketed predicate devices.