



Food and Drug Administration  
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April 4, 2016

Epic Medical Pte. Ltd.  
c/o Mr. Dave Yungvirt  
Third Party Review Group, LLC  
The Old Station House  
24 Lackawanna Place  
Millburn, New Jersey 07041

Re K151650  
Trade/Device Name: SMARTeZ Elastomeric Infusion Pump  
Regulation Number: 21 CFR 880.5725  
Regulation Name: Infusion Pump  
Regulatory Class: II  
Product Code: MEB  
Dated: February 18, 2016  
Received: February 22, 2016

Dear Mr. Yungvirt:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Tina Kiang  
-S

for Erin I. Keith, M.S.

Director  
Division of Anesthesiology, General Hospital,  
Respiratory, Infection Control and  
Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K151650

Device Name

SMARTeZ Pump

Indications for Use (Describe)

The SMARTeZ Pump (Long infusion time article) is intended for continuous infusion of medications for general infusion use, including pain management.

- Routes of administration: intravenous and subcutaneous.

The SMARTeZ Pump (Short infusion time article) is intended for continuous infusion of medications for general infusion use, including antibiotic delivery.

- Route of administration: intravenous.

The SMARTeZ Pump (Chemotherapy article) is intended for continuous infusion of chemotherapy medications.

- Routes of administration: intravenous and intra-arterial.

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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## Section § 5 : 510(k) Summary

**Date Prepared:** April 1, 2016

### 5.1 510(k) Owner Name

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Singapore 238882.

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Email: freddie.lee@epic-med.com

**Contact Person Name:** Mr. Freddie Lee

### 5.2 Device Name & Classification

In accordance with FDA's product classification database, the SMARTeZ Pump is determined to be a Class II device, further details as below table.

**Table 5-1. Classification of SMARTeZ Pump**

<b>Common/Usual Name</b>	Elastomeric Infusion Pump
<b>Proprietary/Trade Name</b>	SMARTeZ Pump
<b>Device Name</b>	Pump, Infusion, Elastomeric
<b>Regulation Description</b>	Infusion Pump
<b>Review Panel</b>	General Hospital
<b>Product Code</b>	MEB
<b>Regulation Number</b>	21 CFR 880.5725
<b>Device Class</b>	II

### 5.3 Predicate Devices

One primary legally marketed device and three (3) secondary legally marketed devices as shown in Table 5-2 were selected as predicate devices for the substantial equivalence discussion. These devices were selected due to the fact that the intended use and technological characteristics of SMARTeZ Pump are equivalent to these devices.

**Table 5-2. Predicate devices SMARTeZ Pump is substantial equivalent (SE\*) with**

Predicate Devices				
<b>510(k) No.</b>	K052117 (Primary)	K071222	K081905	K991513
<b>510(k) Submitter</b>	I-Flow Corporation	Baxter Healthcare Corporation	Westmed, Inc. (B. Braun Medical Inc.)	I-Flow Corporation
<b>Trade Name</b>	I-Flow Elastomeric Pump (Homepump/ Easypump)	Infusor SV and LV Elastomeric Infusion Devices	AccuFlo, AccuFlux	Homepump C- Series

(\*SE: Substantial Equivalence)

### 5.4 Device Description

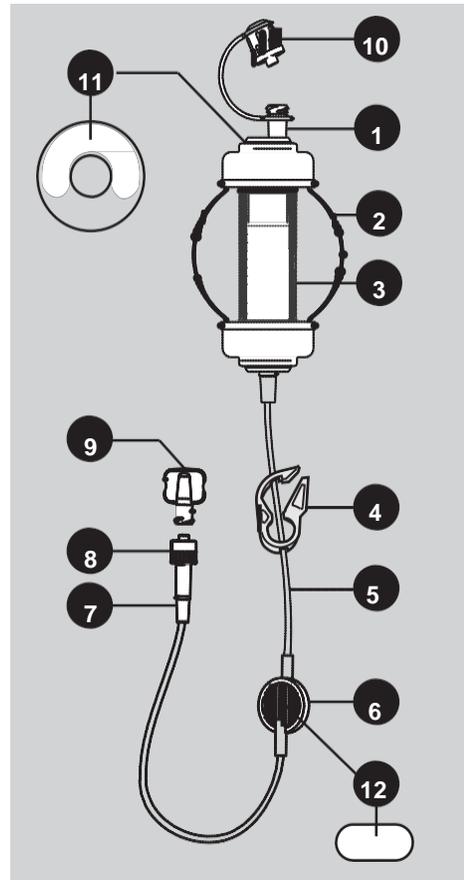
The SMARTeZ Pump, is a single-use disposable, non-electric infusion pump that consists of an elastomeric fluid reservoir as energy source with an integrated administration line (see Figure 5-1). The constriction of elastomeric fluid reservoir drives the medication through the tubing and eventually through a flow restrictor out into the patient connection. Drug products should be stored in their approved containers and closures.

**Figure 5-1. Diagram of the SMARTeZ Pump**

#### SMARTeZ™ Pump

Portable single use elastomeric infusion pump

1. Fill port
2. Outer soft cover
3. Multi-layered elastomeric membrane
4. ON-OFF clamp
5. PVC administration tubing not made from Phthalate (DEHP)
6. Air and particulate eliminating filter
7. Flow restrictor
8. Patient connector
9. Patient end cap
10. Fill port cap (tethered)
11. Labelling - Fill volume & infusion time
12. Labelling - Flow rate



## 5.5 Indications for Use Statements

**The SMARTeZ Pump (Long infusion time article)** is intended for continuous infusion of medications for general infusion use, including pain management.

- Routes of administration: intravenous and subcutaneous.

**The SMARTeZ Pump (Short infusion time article)** is intended for continuous infusion of medications for general infusion use, including antibiotic delivery.

- Route of administration: intravenous.

**The SMARTeZ Pump (Chemotherapy article)** is intended for continuous infusion of chemotherapy medications.

- Routes of administration: intravenous and intra-arterial.

The Indications for Use statement of the SMARTeZ Pump is not identical to the predicate devices; however, the differences in infusion routes do not alter the intended use of the device nor do they affect the safety and effectiveness of the device relative to the predicates. All devices have the same intended use for the continuous infusion of medications.

## 5.6 Technological Characteristics

The SMARTeZ Pump is a non-electrically driven, portable fixed flow rate infusion pump. The flow rate of the device is pre-determined by the manufacturer using Hagen-Poiseuille theory, which calculates the volumetric flow rate of a fluid with certain viscosity passing through a cylindrical pipe.

The device consists of three (3) critical components that control the factors that determine the flow rate: The fluid reservoir, the micro bore tube and the flow restrictor. The fluid reservoir holds the medication to be infused and exert pressure onto the medication as the energy source of the device. The micro bore tube and the flow restrictor on each device are calibrated to match with the fluid reservoir so the medication will pass through them under a fixed pre-determined flow rate.



**5.6.1 Range of Articles (Model Numbers)**

The following devices cleared under K151650 are shown in Table 5-3.

**Table 5-3. Range of SMARTeZ Pump articles (model numbers) cleared under K151650**

Type	Tubing Specifications		No. of products in packaging		Designation	Nominal volume (ml)	Nominal flow rate (ml/h)	Nominal time (h)	Article Number (REF)
	Administration tube	Flow restrictor – Micro bore tube*	Per sterile barrier system	Per protective packaging					
Long Infusion Time Articles/ Model Numbers	OD: 2.4 mm  ID: 1.0 mm  Length: 90 cm	OD: 2.4 mm  ID: 0.1 ~ 0.2 mm  Length: 15 ~ 40 cm	1 ea	12 ea	SMARTeZ 60-5-12h	60	5	12	480011
					SMARTeZ 80-5-16h	80	5	16	480021
					SMARTeZ 125-5-25h	125	5	25	480031
					SMARTeZ 270-10-27h	270	10	27	480041
					SMARTeZ 60-2-30h	60	2	30	480051
					SMARTeZ 120-4-30h	120	4	30	480061
					SMARTeZ 400-10-40h	400	10	40	480071
					SMARTeZ 100-2-50h	100	2	50	480081
					SMARTeZ 270-5-54h	270	5	54	480091
					SMARTeZ 120-2-60h	120	2	60	480101
					SMARTeZ 400-5-80h	400	5	80	480111
					SMARTeZ 100-1.5-67h	100	1.5	67	480121
SMARTeZ 270-4-68h	270	4	68	480131					



Type	Tubing Specifications		No. of products in packaging		Designation	Nominal volume (ml)	Nominal flow rate (ml/h)	Nominal time (h)	Article Number (REF)
	Administration tube	Flow restrictor – Micro bore tube*	Per sterile barrier system	Per protective packaging					
Long Infusion Time Articles/ Model Numbers	OD: 2.4 mm  ID: 1.0 mm  Length: 90 cm	OD: 2.4 mm  ID: 0.1 ~ 0.2 mm  Length: 15 ~ 40 cm	1 ea	12 ea	SMARTeZ 400-4-100h	400	4	100	480141
					SMARTeZ 65-0.5-130h	65	0.5	130	480151
					SMARTeZ 270-2-135h	270	2	135	480161
					SMARTeZ 300-2-150h	300	2	150	480171
					SMARTeZ 100-0.5-200h	100	0.5	200	480181
					SMARTeZ 270-1-270h	270	1	270	480191
Short Infusion Time Articles/ Model Numbers	OD: 2.4 mm  ID: 1.0 mm  Length: 90 cm	OD: 2.4 mm  ID: 0.2 ~ 0.5 mm  Length: 15 ~ 40 cm	1 ea	24 ea	SMARTeZ 100-200-30m	100	200	0.5	481012
					SMARTeZ 250-500-30m	250	500	0.5	481022
					SMARTeZ 50-50-60m	50	50	1	481032
					SMARTeZ 100-100-60m	100	100	1	481042
					SMARTeZ 250-250-60m	250	250	1	481052
					SMARTeZ 250-175-90m	250	175	1.5	481062
					SMARTeZ 100-50-120m	100	50	2	481092
					SMARTeZ 200-100-120m	200	100	2	481112



Type	Tubing Specifications		No. of products in packaging		Designation	Nominal volume (ml)	Nominal flow rate (ml/h)	Nominal time (h)	Article Number (REF)
	Administration tube	Flow restrictor – Micro bore tube*	Per sterile barrier system	Per protective packaging					
Short Infusion Time Articles/ Model Numbers	OD: 2.4 mm  ID: 1.0 mm  Length: 90 cm	OD: 2.4 mm  ID: 0.2 ~ 0.5 mm  Length: 15 ~ 40 cm	1 ea	24 ea	SMARTeZ 250-100-150m	250	100	2.5	481122
					SMARTeZ 250-125-120m	250	125	2	481132
					SMARTeZ 200-200-60m	200	200	1	481142
					SMARTeZ 250-50-300m	250	50	5	481152
	1 ea	12 ea	SMARTeZ 400-200-120m	400	200	2	481071		
			SMARTeZ 500-250-120m	500	250	2	481081		
			SMARTeZ 400-100-240m	400	100	4	481101		
Chemo-therapy Articles/ Model Numbers	OD: 2.4 mm  ID: 1.0 mm  Length: 90 cm	OD: 2.4 mm  ID: 0.1 ~ 0.2 mm  Length: 15 ~ 40 cm	1 ea	12 ea	SMARTeZ C100-2-50h	100	2	50	484011
					SMARTeZ C270-2-135h	270	2	135	484021
					SMARTeZ C120-4-30h	120	4	30	484031
					SMARTeZ C270-5-54h	270	5	54	484041
					SMARTeZ C270-10-27h	270	10	27	484051

(\*Only ranges for each ID and length of micro bore tube are provided in above table. This is due to the fact that every unit piece of flow restrictor is calibrated during production. Flow restrictors of appropriate ID's selected with appropriate cut lengths are the results from this 100% calibration.)



## 5.7 Summary of Substantial Equivalence Discussion

The SMARTeZ Pump is substantially equivalent to the I-Flow Elastomeric Pump (K052117). The intended use and technological characteristics of the SMARTeZ Pump raise no new questions of safety and effectiveness compared to the I-Flow Elastomeric Infusion Pump (K052117).

## 5.8 Summary of Performance Testing

The following performance data was the bases for the substantial equivalence determination.

An assurance case was provided in the submission for the SMARTeZ Pump as recommended in the FDA guidance document, Infusion Pump Total Product Life Cycle.

The stated goal of the assurance case is:

- The design of the SMARTeZ Pump is an adequately safe infusion means in the context of all indications for use, patient types, users, use conditions, environments of use and list of devices cleared under K151650.

The assurance case defined the device system, including the indications for use, system specifications and use environments. The supporting assurance arguments covered the following attributes:

- Adequate design verification/validation,
- Acceptability of risk mitigation,
- Adequate device reliability.

The assurance case and referenced evidence demonstrate that the SMARTeZ Pump functions as designed and can be operated by the user as intended with the instructions provided.

The following evidence was included in the assurance case:

### Functionality



**Table 5-4. Summary of Bench Test Results for Long Infusion Time, Short Infusion Time and Chemotherapy Articles**

Bench Test Completed	Applicable Standard & Clause	Acceptance Criteria	Test Results
Flow Rate Test (Nominal Condition)	<p>ISO 28620:2010, Sub-clause 6.2.</p> <p>The samples were tested for flow rate under conditions specified by manufacturer for which the claimed flow rate accuracy is achieved.</p>	<ul style="list-style-type: none"> <li>The mean flow rate shall have a tolerance of <math>\pm 15\%</math> compared to the nominal flow rate.</li> <li>At least 80% of the nominal volume shall be delivered at an instantaneous flow rate within <math>\pm 50\%</math> of the nominal flow rate.</li> </ul>	<p>Passed.</p> <ul style="list-style-type: none"> <li>All test samples passed both acceptance criteria.</li> <li>It is confirmed through statistical analysis that when the subject device is filled at nominal volume, flow accuracy is within <math>\pm 15\%</math> of the nominal (label) flow rate (at 99% confidence level, lower- and upper-bounds of <math>-0.400\%</math> to <math>+0.151\%</math>) when delivering normal saline at 88 deg F (31 deg C) with pump positioned at 16" (40 cm) below the catheter site.</li> </ul>
Flow Rate Test (Change of Ambient Temperature)	<p>ISO 28620:2010, Sub-clause 6.2.</p> <p>The samples were tested for flow rate with flow restrictor at <math>25 \pm 1^\circ\text{C}</math>.</p>	<ul style="list-style-type: none"> <li>The mean flow rates of samples should be no more than 15% slower when compared with that tested with flow restrictor temperature at <math>31^\circ\text{C}</math>.</li> </ul>	<p>Passed.</p> <ul style="list-style-type: none"> <li>The results show mean flow rate of the samples is 14.07% slower.</li> <li>The results confirmed the IFU claimed temperature effect to flow rate accuracy.</li> </ul>
Flow Rate Test (Change of Solution Viscosity)	<p>ISO 28620:2010, Sub-clause 6.2.</p> <p>The samples were tested for flow rate using 5% Dextrose as control solution.</p>	<ul style="list-style-type: none"> <li>The mean flow rates of samples should be no more than 10% slower when compared with that tested with 0.9% NaCl as control solution.</li> </ul>	<p>Passed.</p> <ul style="list-style-type: none"> <li>The results show mean flow rate of the samples is 9.81% slower.</li> <li>The results confirmed the IFU claimed fluid viscosity effect to flow rate accuracy.</li> </ul>
Flow Rate Test after Resistance to Pressure Test	<p>ISO 28620:2010, Sub-clause 6.2 &amp; 6.3.</p>	<ul style="list-style-type: none"> <li>The mean flow rate shall have a tolerance of <math>\pm 15\%</math> compared to the nominal flow rate.</li> </ul>	<p>Passed.</p> <ul style="list-style-type: none"> <li>All the samples passed both acceptance criteria.</li> </ul>



Bench Test Completed	Applicable Standard & Clause	Acceptance Criteria	Test Results
	<p>The entire fluid reservoir of the samples were under a force of 150N for 5s. After pressure is removed, the samples were tested for flow rate.</p>	<ul style="list-style-type: none"> <li>At least 80% of the nominal volume shall be delivered at an instantaneous flow rate within <math>\pm 50\%</math> of the nominal flow rate.</li> </ul>	<p>Passed.</p> <ul style="list-style-type: none"> <li>The flow rate results were compared with that of the same article (model) from Flow Rate Test at Nominal Condition.</li> <li>The statistical analysis showed the flow rate accuracy was not affected by resistance to pressure test.</li> </ul>
<p>Leak-Proof Test after Resistance to Pressure Test</p>	<p>ISO 28620:2010, Sub-clause 6.3 &amp; 6.5.</p> <p>The entire fluid reservoir of the samples were under a force of 150N for 5s. After pressure is removed, the samples were inspected for leakage.</p>	<p>After resistance to pressure test:</p> <ul style="list-style-type: none"> <li>The device shall remain watertight, and the solution in container shall not become colored.</li> </ul>	<p>Passed.</p> <ul style="list-style-type: none"> <li>All test samples passed the acceptance criteria.</li> </ul>
<p>Leak-Proof Test after Drop Test</p>	<p>ISO 28620:2010, Sub-clause 6.4 &amp; 6.5.</p> <p>The samples were filled with dyed solution then dropped twice from one (1) meter height. After drop, the samples were inspected for leakage.</p>	<p>After drop test:</p> <ul style="list-style-type: none"> <li>The device shall remain watertight, and the solution in container shall not become colored.</li> </ul>	<p>Passed.</p> <ul style="list-style-type: none"> <li>All test samples passed the acceptance criteria.</li> </ul>
<p>Flow Rate Test after Resistance to Traction Test</p>	<p>ISO 28620:2010, Sub-clause 6.2 &amp; 6.6.</p> <p>The samples were applied a force of 15N for 15s between each end of the device. After force is</p>	<ul style="list-style-type: none"> <li>The mean flow rate shall have a tolerance of <math>\pm 15\%</math> compared to the nominal flow rate.</li> <li>At least 80% of the nominal volume shall be delivered at an</li> </ul>	<p>Passed.</p> <ul style="list-style-type: none"> <li>All test samples passed both acceptance criteria.</li> <li>The flow rate results were compared with that of the same article (model) from Flow Rate Test at Nominal Condition.</li> </ul>



Bench Test Completed	Applicable Standard & Clause	Acceptance Criteria	Test Results
	removed, the samples were tested for flow rate.	instantaneous flow rate within $\pm 50\%$ of the nominal flow rate.	<p>Passed.</p> <ul style="list-style-type: none"> <li>The statistical analysis showed the flow rate accuracy was not affected by resistance to pressure test.</li> </ul>
Leak-Proof Test after Resistance to Traction Test	<p>ISO 28620:2010, Sub-clause 6.5 &amp; 6.6.</p> <p>The samples were applied a force of 15N for 15s between each ends of the device. After force is removed, the samples were inspected for leakage.</p>	<p>After resistance to traction test:</p> <ul style="list-style-type: none"> <li>The device shall remain watertight, and the solution in container shall not become colored.</li> </ul>	<p>Passed.</p> <ul style="list-style-type: none"> <li>All test samples passed the acceptance criteria.</li> </ul>
Flow Rate Test after Refrigeration	<p>ISO 28620:2010, Sub-clause 6.2.</p> <p>The samples were filled and refrigerated (2~8°C) for 72 hours. After return to room temperature, the samples were tested for flow rate.</p>	<ul style="list-style-type: none"> <li>The mean flow rate shall have a tolerance of <math>\pm 15\%</math> compared to the nominal flow rate.</li> <li>At least 80% of the nominal volume shall be delivered at an instantaneous flow rate within <math>\pm 50\%</math> of the nominal flow rate.</li> </ul>	<p>Passed.</p> <ul style="list-style-type: none"> <li>All test samples passed both flow rate and leak integrity acceptance criteria.</li> <li>The flow rate results were compared with that of the same article (model) from Flow Rate Test at Nominal Condition.</li> <li>The statistical analysis showed the flow rate accuracy was not affected by refrigeration.</li> </ul>



Bench Test Completed	Applicable Standard & Clause	Acceptance Criteria	Test Results
Leak-Proof Test after Refrigeration	<p>ISO 28620:2010, Sub-clause 6.2.</p> <p>The samples were filled and refrigerated (2~8°C) for 72 hours. After return to room temperature, the samples were inspected for leakage.</p>	<p>After refrigeration:</p> <ul style="list-style-type: none"> <li>The device shall remain watertight, and the solution in container shall not become colored.</li> </ul>	<p>Passed.</p> <ul style="list-style-type: none"> <li>All test samples passed the acceptance criteria.</li> </ul>
Retrograde Flow of Infusate Test	<p>The infusion completed samples were applied with a back pressure from distal connector to observe the retrograde flow of infusate.</p>	<p>Retrograde flow of infusate should not be observed when back pressure applied <math>\leq 0.34\text{bar}</math> (5 psi, the maximum possible back pressure during the actual use).</p>	<p>Passed.</p> <ul style="list-style-type: none"> <li>The back pressure that retrograde flow of infusate observed was 0.8bar (11.6 psi), which is double that of the acceptance criteria.</li> </ul>
Flow Rate Test under Non-Ambient Pressure (Influence of Routes of Administration)	<p>ISO 28620:2010, Sub-clause 6.2.</p> <p>The samples were tested for flow rate under conditions specified by manufacturer for which the claimed flow rate accuracy is achieved.</p>	<p>To study the influence on flow rate from the following routes of infusion: intravenous, intra-arterial and subcutaneous routes; and to confirm that:</p> <ul style="list-style-type: none"> <li>The mean flow rate shall have a tolerance of <math>\pm 15\%</math> compared to the nominal flow rate.</li> <li>At least 80% of the nominal volume shall be delivered at an instantaneous flow rate within <math>\pm 50\%</math> of the nominal flow rate are maintained, independent of the 3 routes of infusion administered.</li> </ul>	<p>Passed.</p> <ul style="list-style-type: none"> <li>The influence on flow rate from the following routes of infusion: intravenous, intra-arterial and subcutaneous routes; were established. It is confirmed that flow accuracy of <math>\pm 15\%</math> of the nominal (label) flow rate is maintained, independent of the 3 routes of infusion administered.</li> </ul>



Bench Test Completed	Applicable Standard & Clause	Acceptance Criteria	Test Results
<p>Performance /Functionality Testing for Chemotherapy Articles</p>	<p>ISO 28620:2010, Sub-clauses 6.2, 6.3, 6.4, 6.5 and 6.6.</p> <p>Note: In chemotherapy articles the range of flow rates and fill volume combinations are fully represented in all the bench test protocols.</p>	<ul style="list-style-type: none"> <li>• Flow accuracies, in nominal conditions, after resistance to pressure, after resistance to traction, under non-ambient pressure and after refrigeration:               <ul style="list-style-type: none"> <li>○ The mean flow rate shall have a tolerance of <math>\pm 15\%</math> compared to the nominal flow rate.</li> <li>○ At least 80% of the nominal volume shall be delivered at an instantaneous flow rate within <math>\pm 50\%</math> of the nominal flow rate.</li> </ul> </li> <li>• The device shall remain watertight after resistance to pressure, after resistance to traction, after being dropped and after refrigeration.</li> <li>• Retrograde flow of infusate should not be observed when back pressure applied <math>\leq 0.34\text{bar}</math> (5 psi, the maximum possible back pressure during the actual use).</li> </ul>	<p>Passed.</p> <ul style="list-style-type: none"> <li>• All test samples passed all acceptance criteria.</li> </ul>

All the performance test results and their evaluations met the acceptance criteria.

## **5.9 Human Factors and Usability Testing**

The design of Human Factors (HF) testing is supported by the analysis of the hazards arising from human factors/usability in operating the device. The critical operating tasks included dilution, filling, priming and infusing, and the HF testing results show that there were no user errors identified even though the participants were not coached.

## **5.10 Shelf-life Testing to Verify Sterility and Performance at Expiry**

The SMARTeZ Pump is provided sterile and not to be re-sterilized. The sterilization process uses the traditional method of Ethylene Oxide (EO) with the subject devices placed in a fixed chamber.

The Ethylene Oxide (EO) sterilization process for SMARTeZ Pump was validated using the overkill approach with compliance to Annex B of ISO 11135:2014 to achieve a Sterility Assurance Level (SAL) of  $10^{-6}$ .

The subject device was tested for a 3-year shelf-life using accelerated conditioning prescribed in ASTM F1980-07 (2011), “Standard guide for accelerated aging of sterile barrier systems for medical devices, reapproved 2011”, and with test methods prescribed in F 1929-12, “Standard test method for detecting seal leaks in porous medical packaging by dye penetration” and F1886/ F1886M-09, “Standard test method for determining integrity of seals for flexible packaging by visual inspection”.

It was verified that the subject device packaging integrity and functional attributes remained within specifications. A real-time protocol was evaluated to assure ongoing stability.

## **5.11 Biocompatibility Testing**

The biocompatibility evaluation and chemical characterization activities were performed for SMARTeZ Pump in its final finished presentation intended for the market. The SMARTeZ Pump was evaluated to have complied with the following:

- “Use of International Standard ISO 10993-1, ‘Biological Evaluation of Medical Devices Part 1: Evaluation and Testing’, Draft Guidance for Industry and Food and Drug Administration Staff”.
- ANSI/AAMI/ISO 10993-1:2009/(R)2013, “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process”.
- FDA TPLC guidance “Infusion Pumps Total Product Life Cycle - Guidance for Industry and FDA Staff” issued on: December 2, 2014, Biological Safety sub-section.



The biocompatibility evaluation and chemical characterization activities were performed for SMARTeZ Pump. The SMARTeZ Pump was evaluated and have complied with the “Use of International Standard ISO 10993-1, “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing”, Draft Guidance for Industry and Food and Drug Administration Staff”, ANSI/AAMI/ISO 10993-1:2009/(R)2013, “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process” and FDA TPLC guidance “Infusion Pumps Total Product Life Cycle - Guidance for Industry and FDA Staff” issued on: December 2, 2014, Biological Safety sub-section.

**Test results:**

**Table 5-5. Summary of Biocompatibility Tests and Chemical Characterizations**

<b>Test</b>	<b>Method*</b>	<b>Result</b>
Leachables/Extractables	ISO 10993-18	No leachable/extractable hazardous substances and heavy metals
Cytotoxicity	ISO 10993-5	Non-cytotoxic
Sensitization	ISO 10993-10	Non-sensitizing
Irritation or intracutaneous reactivity	ISO 10993-10	Intracutaneously non-irritating
System toxicity (acute)	ISO 10993-11	Systemically non-toxic (acute)
Haemocompatibility	ISO 10993-4	Non-hemolytic

\*Method refers to testing sponsored by Epic Medical Pte. Ltd.

The biocompatibility studies and chemical characterization conducted on sterile SMARTeZ Pump in its final finished presentation intended for the market have confirmed the acceptable biocompatibility and leachables/extractables statuses of the device.

## **5.12 Conclusion**

The overall evaluation of SMARTeZ Pump, the subject device, demonstrated that it is substantially equivalent with the predicate devices.