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SECTION I
SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) SUMMARY FOR SAFETY AND EFFECTIVENESS OF THE SIGMA SYRINGE DELIVERY SYSTEM

This summary is intended to support SIGMA's claim of substantial equivalence. The summary is part of a Premarket Notification to manufacture and market a new device that is similar to legally marketed predicated devices for comparison of substantial safety and effectiveness.

1.0 INTRODUCTION

The SIGMA Syringe Delivery System includes a device : Multi-Doser Rev. I, Multi-Doser Rev. II, Single-Doser Rev. I-10, or the Single-Doser Rev. I-20 (herein referred to as an Infuser) used with the SIGMA 99400 Rate-Control Microbore Extension Set (herein referred to as the Rate-Control Set). This system incorporates the use of the Infuser as the energy source to propel fluid through the Rate-Control Set. Utilizing the administration set to control the rate of fluid delivery is identical, to the following legally marketed devices :

1) Medifuse™ from 3M
2) Band-It from I-Flow®
3) Side-Kick™ from I-Flow®

2.0 DESCRIPTION

The SIGMA Syringe Deliver Systems are syringe infusion pumps that operate using two principles for delivery - a spring and resistive tubing. The mechanical principle is produced by relaxing spring force. The devices are strictly mechanical in operation and do not require the execution of software. This type of infusion pump is used to pump fluids into a patient in a controlled manner. The models are designed specifically for the controlled, parenteral infusion of non-rate critical drugs and medications. The SIGMA infusers are best identified and described in Title 21, Part 880.5725, of the Code of Federal Regulations, as classification Class II, Infusion Pump.

The "SIGMA Syringe Infusion System" is a combination of three components : 1) an Infuser, 2) Rate-Control Extension Set and 3) syringes(supplied by the user). All three components act together as a system. The infuser acts as the energy force that pushes fluid from the syringe, the fluid reservoir, through a Rate-Control IV Extension Administration Set, that controls the rate of the fluid delivery to the patient.

The three components are as follows :

1) Infuser (Multi-Doser Rev. I, Multi-Doser Rev. II, Single-Doser Rev. I-10, or the Single-Doser Rev. I-20) - The Infuser is a mechanical syringe infuser that utilizes a stainless steel spring as the pump mechanism. The infuser's function, in the system, is to push fluid from the syringe (the fluid reservoir) with a linear force.

The operating mechanism (pump mechanism) is a spring. The spring is compressed and as it expands back to its relaxed state, it pushes or drives the syringe plunger. The method of delivery is consistent with all of the devices.

2) Sigma 99400 Rate-Control Microbore Extension Set - This is the component that controls the flow rate. As fluid is pushed from the syringe to the patient, it travels through the Rate-Control Microbore Extension Set. As the fluid travels through the set, its flow rate is controlled by the inner diameter and the length of the set - the resistive value.

The micro inner diameter of .0125" and 66 inch length to creates a flow resistance, which controls the rate of delivery. The set is Non-DEHP PVC. Its fluid path is sterile, non-toxic, non-pyrogenic. (Set Labeling - Section B) (Set Drawing - Section D, 3.3.2).

3) The Syringe - The syringe is the drug reservoir. SYRINGES ARE PROVIDED BY THE USER AND ALTHOUGH THEY ARE A COMPONENT IN THE SYSTEM, THEY ARE NOT PART OF THIS DEVICE OR FOR EVALUATION IN THIS SUBMISSION. The system uses standard plastic, luer tip B-D™ or Monoject™ syringes. The syringe is the medication container - replacing mini-bags. The syringe is simply a source container for the medication - drugs or dosage do not need to be changed. This principle is consistent with the syringe pump systems, which have been successfully marketed for a number of years.

3.0
INTENDED USE

The "Sigma Syringe Delivery System" is designed for the controlled intermittent administration of small volume intravenous fluid medications for the treatment of human or animal subjects. Its specific design characteristics limit the device's use to slow, non-rate critical, small volume parenteral applications, identical to the predicate devices.

4.0
COMPARISON TO LEGALLY MARKETED DEVICES

The SIGMA Syringe Delivery System utilizes identical principles as the predicated devices - an energy force propelling fluid through an IV administration set that controls the rate of fluid delivery. The material used to manufacture the IV set is similar or identical. The differences between the devices are the drug reservoir, the pump mechanism and general operation of the device. These differences in no way affect the safety and effectiveness of the system.

Refer to the following table for a comparison of the SIGMA Syringe Delivery System with the predicated legally marketed devices.

Mode of Operation

Parameter	Sigma Mult-Doser Rev. I	Sigma Multi-Doser Rev. II
Device Type	Mechanical spring syringe infusion pump	Mechanical spring syringe infusion pump
Mode and Principle of Operation	Applied mechanical spring force to drive syringe through tubing that controls the flow rate	Applied mechanical spring force to drive syringe through tubing that controls the flow rate
Drug Reservoir	Syringe	Syringe

Parameter	Sigma Single-Doser R. I-10	Sigma Single-Doser R. I-20
Device Type	Mechanical spring syringe infusion pump	Mechanical spring syringe infusion pump
Mode and Principle of Operation	Applied mechanical spring force to drive syringe through tubing that controls the flow rate	Applied mechanical spring force to drive syringe through tubing that controls the flow rate
Drug Reservoir	Syringe	Syringe

Parameter	3M Medifuse	I-Flow Bandit
Device Type	Mechanical spring syringe infusion pump	Elastic latex band syringe infusion pump
Mode and Principle of Operation	Applied mechanical spring force to drive syringe through tubing that controls the flow rate	Applied force utilizing an elastic latex band to drive syringe through tubing that controls the flow rate
Drug Reservoir	Syringe	Syringe

Parameter	I-Flow SideKick
Device Type	Mechanical spring infusion pump
Mode and Principle of Operation	Applied mechanical spring force which compresses a mini-bag and forces fluid through tubing that controls the flow rate
Drug Reservoir	Special IV Bag

Flow Rates

Parameter	Sigma Mult-Doser Rev. I	Sigma Multi-Doser Rev. II
Flow Rate	Flow Rate : Monoject 60cc - 21 ml/hr B-D 60cc - 18 ml/hr	Same as the Multi-Doser Rev I
Flow Rate Based on :	Sterile Water	Sterile Water
Pressure	Typical 9.6 PSI; Max 13.5 PSI	Same as the Multi-Doser Rev I

Parameter	Sigma Single-Doser R. I-10	Sigma Single-Doser R. I-20
Flow Rate	Flow Rate - 24 ml/hr	Flow Rate - 22 ml/hr
Flow Rate Based on :	Sterile Water	Sterile Water
Pressure	Same as the Multi-Doser Rev I	Same as the Multi-Doser Rev I

Flow Rates (continued)

Parameter	3M Medifuse	I-Flow Bandit
Flow Rate	*20 - 40 minute infusion : Dose Syringe Set 3ml 20cc Purple 5ml 10/12cc Purple 10ml 30/35cc Gray 20ml 30/35cc Red 20ml 30/35cc Gray 30ml 30/35cc Red *50 - 70 minute infusion : Dose Syringe Set 3ml 10/12cc Pink 5ml 30/35cc Purple 10ml 10/12cc Purple 30ml 30/35cc Gray	Set number 5000861 - over 15 minutes with a B-D 10cc syringe Set number 5000862 - over 30 minutes with a B-D 10cc syringe
Flow Rate Based on :	5% Dextrose	Sterile Water
Pressure	Not Available	Not Available

Parameter	I-Flow SideKick
Flow Rate	50 ml/hr 100 ml/hr 200 ml/hr
Flow Rate Based on :	Not Available
Pressure	8 psi

Infusion Time

Parameter	Sigma Mult-Doser Rev. I	Sigma Multi-Doser Rev. II
Infusion Time	*Infusion Time : Monoject 60cc Typical - 30 minutes Range - 22-37 minutes *Infusion Time : B-D 60cc Typical - 35 minutes Range - 22-37 minutes *based on infusing 98% of the dose at an operating temp (ambient & fluid) of 62°F - 82°F, a head height of 0-3 feet and a venous pressure of 0 - 30 mmHg.	Same as the Multi-Doser Rev I
Infusion Time Based on :	Sterile Water	Sterile Water

Parameter	Sigma Single-Doser R. I-10	Sigma Single-Doser R. I-20
Infusion Time	*Infusion Time : Typical - 25 minutes Range - 18-32 minutes *based on infusing 98% of the dose at an operating temp (ambient & fluid) of 62°F - 82°F, a head height of 0-3 feet and a venous pressure of 0 - 30 mmHg.	*Infusion Time : Typical - 55 minutes Range - 40-70 minutes *based on infusing 98% of the dose at an operating temp (ambient & fluid) of 62°F - 82°F, a head height of 0-3 feet and a venous pressure of 0 - 30 mmHg.
Infusion Time Based on :	Sterile Water	Sterile Water

Infusion Time (continued)

Parameter	3M Medifuse	I-Flow Bandit
Infusion Time	*20 - 40 minute infusion : Dose Syringe Set 3ml 20cc Purple 5ml 10/12cc Purple 10ml 30/35cc Gray 20ml 30/35cc Red 20ml 30/35cc Gray 30ml 30/35cc Red *50 - 70 minute infusion : Dose Syringe Set 3ml 10/12cc Pink 5ml 30/35cc Purple 10ml 10/12cc Purple 30ml 30/35cc Gray	Set number 5000861 - over 15 minutes with a B-D 10cc syringe Set number 5000862 - over 30 minutes with a B-D 10cc syringe
Infusion Time Based on :	5% Dextrose	Sterile Water

Parameter	I-Flow SideKick
Infusion Time	50 ml/hr 100 ml/hr 200 ml/hr
Infusion Time Based on :	Not Available

Accuracy

Parameter	Sigma Mult-Doser Rev. I	Sigma Multi-Doser Rev. II
Accuracy	±23% w/ Monoject 60cc & 28.5% w/ B-D 60cc - for a 95% confidence level using sterile water at an operating temperature(ambient and fluid) of 62°F - 82°F ,0-3 feet above the IV site and venous pressure of 0-30 mmHg.	Same as the Mullti-Doser Rev I

Parameter	Sigma Single-Doser R. I-10	Sigma Single-Doser R. I-20
Accuracy	±28% for a 95% confidence level using sterile water at an operating temperature (ambient and fluid) of 62°F - 82°F ,0-3 feet above the IV site and venous pressure of 0-30 mmHg.	±27% for a 95% confidence level using sterile water at an operating temperature (ambient and fluid) of 62°F - 82°F ,0-3 feet above the IV site and venous pressure of 0-30 mmHg.

Parameter	3M Medifuse	I-Flow Bandit
Accuracy	Not Available.	+/- 15% at 95% confidence interval when used with a B-D syringe under operating conditions of 72 degrees +/- 2 degrees within 1 foot above or below the IV site.

Parameter	I-Flow SideKick
Accuracy	Not Available.

Comparison of Physical Specifications

Parameter	Sigma Mult-Doser Rev. I	Sigma Multi-Doser Rev. II
Pump Mechanism and Major System Subassemblies or Components	Compression Spring - Frame and Tracks - Drive Spring - Release Button and Spring - Pusher and Pusher Block - Grips - Hanger	Compression Spring - Frame and Tracks - Drive Spring - Release Button and Spring - Pusher and Pusher Block - Grips - Anti-Siphon Latch - Hanger
Dimensions	1 3/4 (H) x 2 7/8 (W) x 8 (L) inches 42 (H) x 74 (W) x 224 (L) mm	1 3/4(h)x2 7/8(w)x13 3/4(L) inches 42 (H) x 74 (W) x 374 (L) mm
Weight	12.5 oz (.35 kg)	1.3 lb (.54 kg)

Parameter	Sigma Single-Doser R. I-10	Sigma Single-Doser R. I-20
Pump Mechanism Major System Subassemblies or Components	Compression Spring - Frame - Pusher Block - Drive Spring - Pusher - Syringe Locator - Latching Components - Hanger	Compression Spring - Frame - Pusher Block - Drive Spring - Pusher - Syringe Locator - Latching Components - Hanger
Dimensions	OPENED : 7/8(h) x1 3/4(w)x 11 5/8 (L) inches 23 (H) x 45 (W) x 296 (L) mm CLOSED : 7/8 (H) x 1 3/4 (W) x 7(L) inches 23 (H) x 45 (W) x 179 (L) mm	OPENED : 1 1/8(h)x 2(w)x 14 1/4 (L) inches 30 (H) x 51 (W) x 375 (L) mm CLOSED : 1 1/8(h)x 2(w)x 9 1/4 (L) inches 30 (H) x 51 (W) x 235 (L) mm
Weight	5.1 oz (.15 kg)	6.2 oz (.18 kg)

Comparison of Physical Specifications (continued)

Parameter	3M Medifuse	I-Flow Bandit
Pump Mechanism Major System Subassemblies or Components	Spring - Cover - Chassis Track - Set-Housing Cradle - Locking Tabs - Syringe Clamp - Spring Guide ad Push Rods - Negator Spring and Housing - Glide Wheels	Elastic Latex Band - Syringe Driver - Elastic Latex Band - Syringe Tip Cradle
Dimensions	2 (H) x 2.5 (W) x 13 (L) inches 5 (H) x 6.25 (W) x 32.5 (L) cm	Not Available
Weight	1 lb (.45 kg)	0.4 oz (.01 kg)

Parameter	I-Flow SideKick
Pump Mechanism Major System Subassemblies or Components	Spring - Spring - Top Half - Bottom Half - Pusher
Dimensions	50 ml Infuser Height - 1.87 in. Diameter - 3.7 in. 100 ml Infuser Height - 2.1 in. Diameter - 4.0 in.
Weight	(filled) 50 ml: 8.7 oz ; 100 ml: 11.5 oz

4.1
Technological Differences

4.1.1
Multi-Doser - multiple dosing capabilities

Through the use of multiple dosing the IV fluid path to the patient is not broken into multiple times. The concept of the Multi-Doser is to compound a complete drug regimen or therapy into one drug reservoir and allow the infuser to deliver the correct amount of fluid, containing a dose, at the appropriate interval. Thus, the patient's IV is not broken during the drug therapy. When single dosing, the patient's IV fluid path is broken into for each interval of the drug regimen, as the spent container is changed for the next dose.

Another advantage of the Multi-Doser is that only one dose can be administered at a time. By design, it is impossible to deliver more than one 10 cc dose at a time. This has been a problem with the electronic syringe pumps that allow the nurse to preprogram multiple doses. The potential exists for the inadvertent delivery of an entire 24 hour supply of drug at one time due to user error. The syringe pump offers better accuracy, but the difference in accuracy between the SIGMA Syringe Delivery System and the syringe pumps is clinically insignificant for the specific drugs that will be used for this system. It is clinically significant if the patient receives the entire 24 hour supply of drug at one time. Each activation of the Multi-Doser can only deliver a single 10cc volume of fluid which represents one dose of drug.The device cannot be set to deliver excessive doses of drug and is sufficiently simple to allow for the patient to use in the ambulatory setting.

4.1.2
The Drug Reservoir Can Be Secured in the Infuser and not Infuse

The system is designed to allow the Pusher block to move from a secured position not infusing, to a secured infusing position, to a complete infusion secured position. The predicated devices move from a secured infusing to a secured complete position or require the user to open a clamp for fluid delivery.

5.0
NON-CLINICAL TEST SUPPORTING SAFETY AND EFFECTIVENESS

The non-clinical tests for this device supports the Intended Use of this product. The Intended use for this product is the infusion of non-rate critical intermittent small volume parenteral drugs. Since the predicated devices use the same principle for delivery, specific drugs, are legally marketed, and the SIGMA Syringe Delivery System performs identically and the testing confirms its performance specifications, then it is safe and effective.

5.1
Bench Data Supporting Safety and Effectiveness

The bench data that was performed to prove the devices efficacy. The data was also formatted after the requirements necessary to meet the AAMI standard - ANSI/AAMI D26-1996.

The following data was gathered on the SIGMA Syringe Delivery System :

1) Infusion Time
   Effects of pressure (head height), temperature, Drive Spring variation and syringe to syringe variation.
2) Infusion Time Accuracy
3) Uncontrolled Flow
4) Drop Test
5) Environmental Test
6) Pull Test

5.1.1
Infusion Time

The bench data, from the confirmation testing to determine the Infuser's Infusion Time, is important to substantiate its efficacy. As indicated in Section D 2.3 Specific Drugs, the drugs that will be delivered with this system are non-rate critical, but should be infused over a period of time, at least 20-40 minutes. Therefore, if our system demonstrated this time interval in testing, then we could conclude that it is efficacious for its intended use.

We chose sterile water as the fluid to conduct our tests for two reasons. First, sterile water is the primary reconstitution agent. Secondly, viscosity also affects the infusion time, and we know that no drug will be less viscous than water, therefore we know that water is our fastest variable. Again, our emphasis is to be certain that the fastest infusion time is 20 minutes. If water doesn't infuse faster than 20 minutes, then we could conclude that the drugs intended to be used with this system will not infuse faster than 20 minutes.

All of the tests performed were conducted with sterile water, the SIGMA 99400 Rate-Control Microbore Extension Set, each syringe filled to 40cc and each Infuser actuated four times to facilitate each delivery interval.

The SIGMA 99400 Rate-Control Microbore Extension Sets used for the testing were randomly selected and identified. The sets were determined to have the same resistive value - combination of set length and inner diameter - which eliminated the sets as a variable. Where as the set was not a variable, the syringe to syringe variation had the largest impact to the system. As a result of this variation, we substantiated our infusion time and made our accuracy claims specific to each syringe manufacturer. Our Bench Data was also segregated by syringe.

Effect of Spring Force

The first set of bench tests involved 18 Infusers. The goal was to measure the effect of spring force variation. The temperature was set at an ideal 72° F, the infusers were positioned at a 0 head height, so that temperature and head height (pressure) would not be a variable. The eighteen infusers tested included : 3 with a low spring force and Monoject 60cc syringes, 3 with a low spring force and B-D 60cc syringes, 3 with a nominal spring force and Monoject 60cc syringes, 3 with a nominal spring force and B-D 60cc syringes, 3 with a high spring force and Monoject 60cc syringes, and 3 with a high spring force and B-D 60cc syringes. The infusion time increased with a low spring force - Monoject 60cc increased by 4% and B-D 60cc by 28%. When the high spring force was tested, the infusion time decreased by 11% when used with a Monoject 60cc, the infusion time increased by 2% when used with a B-D 60cc. Even with spring force variation, the recorded infusion time demonstrated that the System was in our specified range and safe and effective for its intended use - greater than 20 minutes and a typical infusion time of 25-40 minutes.

Temperature Variation

The second set of bench tests involved six infusers all at a zero head height, nominal spring force and in an operating temperature (ambient and fluid) of 82° F. This was done to measure the effect of high temperatures. This resulted in a 12% decreased infusion time variation with Monoject 60cc Syringes and a 15% decreased infusion time with B-D 60cc syringes. Fluid was determined to flow faster. However, the infusion time was still within a safe and effective range. The average for Monoject syringes was 25.3 minutes and the average for B-D syringes was 29.8 minutes.

The third set of bench tests involved six infusers all at a zero head height, nominal spring force and in an operating temperature (ambient and fluid) of 62° F. This was done to measure the effect of low temperatures. This resulted in a 20% increased variation with a Monoject 60cc Syringe, but the infusion time decreased by 4% with the B-D 60cc Syringe. The infusion time was still within the safe and effective range. The average for Monoject syringes was 34.6 minutes and the average for B-D syringes was 33.5 minutes.

Head Height Variation

The fourth set of bench tests involved six infusers at +24 inches, nominal spring force and an ideal operating temperature of 72° F. This was done to measure the effect of head height and negative pressure. This resulted in a 13% decreased infusion time with a Monoject 60cc Syringe and a 13% decrease with a B-D 60cc Syringe. The average for Monoject syringes was 24.9 minutes and the average for B-D syringes was 30.4 minutes. The infusion time was still within a safe and effective range.

The fifth set of bench tests involved six infusers at -24 inches, nominal spring force and an ideal operating temperature of 72° F. This was done to measure the effect of positive pressure. This resulted in an 8% increased infusion time with a Monoject 60cc Syringe and a 12% increase with B-D 60cc Syringes. The average for Monoject syringes was 30.9 minutes and the average for B-D syringes was 39.1 minutes. The infusion time was still within the safe and effective range.

The confirmation bench test data yielded the following performance :

Syringe	Typical	Range	Average Flow Rate
*B-D™ 60 cc	35 mins	25 - 45 mins	18 ml/hr
*Monoject™ 60 cc	30 mins	22 - 37 mins	21 ml/hr

*Infusion times have been determined using sterile water at an operating temperature (ambient and fluid) of 62° F to 82° F, from the level of the IV site up to three feet above the IV site and based on a venous pressure of 0 to 30 mmHg. Infusion times are based on infusing 98% of the dose.

Conclusions

The Bench Data proved that the system met our specifications. The conformation tests demonstrated that the SIGMA Syringe Infusers can be safely and effectively used for their intended use, for the intended drugs. The Bench Testing was performed on the Multi-Doser Rev. I. The principles for delivery and the tubing is the same for all of the Infusers - the Multi-Doser Rev. II is actually identical. Where the systems differ is in the syringes each system uses. The varying syringes present varying pressures and delivery flow rates. The spring force for each spring compensates for that difference. As a result, the flow profile and characteristics are similar for each Infuser, even though the flow rates still vary. In summary, the Infusers are similar and perform similarly and would yield the same results as the Multi-Doser Rev. I.

In conclusion, the test indicated that, with all of the variables combined, the SIGMA Syringe System's infusion time is between 20-45 minutes. The specific drugs that will be used in the system are similarly and presently used. Even though these drugs are non-toxic and non-rate critical, they will be routinely infused between 20-40 minutes. Through the use of sterile water in our tests, we proved that our fastest infusion time will be 20 minutes and that our typical infusion time is 30-35 minutes. Therefore, we can conclude that the SIGMA Syringe System can be safely used to administer the intended drugs for this system.

5.1.2
Infusion Time Accuracy

Based on the Bench Test data, our accuracy is claimed as the following:

Syringe	Size	Time to Infuse	Typical	Accuracy
*B-D™	60 cc	25 - 45 mins	35 mins	±28.5%
*Monoject™	60 cc	22 - 37 mins	30 mins	±23%

*The accuracy has been determined at a 95% confidence interval using sterile water at an operating temperature (ambient and fluid) of 62° F to 82° F, from the level of the IV site up to three feet above the IV site and based on a venous pressure of 0 to 30 mmHg.

5.1.3
Uncontrolled Flow

To validate the safety and effectiveness of the Infusers, we had to be certain that if the device was used incorrectly that it would not harm the patient. Our major concern was that the syringe could be loaded incorrectly and possibly siphon. We evaluated the system for uncontrolled siphoning or uncontrolled fluid flow if the syringe was loaded into the infuser incorrectly.

The SIGMA Syringe Delivery System meets the AAMI standard, ANSI/AAMI D26-1996 for uncontrolled flow protection. For uncontrolled flow to occur, the operator would need to execute two distinct actions. First the operator would have to remove the syringe from the device and then the operator would have to elevate the syringe above the IV site, to the maximum extension of the Rate-Control Set.

Our testing demonstrated that, with a minimal venous pressure, free flow did not occur - even with the syringe removed from the device and hung five feet above the patient's IV site.

The first test involved a 60cc syringe with the plunger removed (to simulate zero friction of the plunger) elevated to a five foot head height, the maximum extension of the Rate-Control Set, and a simulated zero venous pressure. The uncontrolled flow rate was substantially lower (at least 25% of the nominal) than our nominal specified flow rate. For example, our nominal flow rate for a Monoject™ syringe is 21 ml/hr and the flow rate with the plunger removed at five feet is 4 ml/hr. However, this could not occur in a clinical setting because there will always be friction on the syringe plunger.

For the second test we elevated both 60cc Monoject™ and 60cc B-D™ syringes to a four foot head height, filled with 10cc of sterile water, and a simulated zero venous pressure. Only one syringe exhibited flow. A 60cc Monoject™ syringe (Monoject™ has the lowest friction of the two manufacturers) exhibited very slow flow, 4cc over a 3 hour period (1.3 ml/hr).

For the last test, we lowered the syringes to a two foot level and filled them with 10cc of sterile water. This would simulate the devices at a five foot head height with a minimal venous pressure. The result was zero flow in a 24 hour period. Therefore, we concluded that as long as the patient has a venous pressure and the syringe has any friction, then uncontrolled flow could not occur. Additionally, even if flow could occur, as the case when we removed the plunger from the syringe, due to slow delivery (25% of the nominal infusion rate) and drugs used, it would not present harm to the patient. In either case, the dynamics of the system lend itself to safe and effective use.

5.1.4
Drop Test

Device was dropped six times from six feet onto a hard tile/concrete floor and was fully functional afterward.

5.1.5
Environmental Test

One liter of solution containing 5% Dextrose was spilled on the infuser and allowed to dry for a 72 hour period. The device was fully functional afterward, the 5% dextrose did not affect the performance of the device.

5.1.6
Pull Test
The Rate-Control Microbore Sets are pull tested and meet the required 4 lbs. of force.

5.2
Safe and Effective Operation

The SIGMA Syringe System is intended for the infusion of non-rate critical intermittent small volume drugs that have a large therapeutic margin but are non-toxic and known for safe and effective use. The bench testing proved that the system meets our specifications. Our specifications are substantially equivalent to legally marketed systems. Additionally, our specifications meet the AAMI standard (ANSI/AAMI ID26-1996) and are consistent with currently established safe IV drug therapy practice.

Based on the bench data we can conclude that the system is safe and effective. However, the Infuser will not be used in laboratory conditions. Therefore, we must consider the user interface and user error. The device is simple and easy to use and is inherently safe to use.

The following are possible user errors and how the system is safe and effective :

1) Incorrectly Loading the Syringe - Incorrectly loading the syringe would result in the syringe being ejected from the Infuser. In which case, the clinician would have to reload the Infuser correctly.

2) Syringe Loaded in the Infuser Correctly, but not Actuated to Infuse the Dose - If the syringe is loaded into the Infuser correctly and the clinician doesn't actuate the device, the Anti-Siphon Catches prevent the syringe from moving. The device will remain in the ready to infuse position until the clinician initiates the infusion.

3) Syringe Loaded in the Infuser and Not Engaged into the Anti-Siphon Catches - The concern here would be siphoning or uncontrolled flow. The bench testing we performed demonstrated that as long as the patient has a venous pressure and the syringe has any friction, then uncontrolled flow could not occur. Even if flow could occur, due to slow delivery (25% of the nominal infusion rate) and the drugs used, it would not present harm to the patient. In either case, the dynamics of the system lend itself to safe and effective use.

4) Incorrect IV Administration Set - The specific drugs that will be used in this system are non-rate critical. The set and infuser are a system that is intended to be used together. The labeling for the system indicates that the set is dedicated to the system. The Multi-Doser Rev. II and the Single-Dosers have a syringe locator. The syringe locator works in conjunction with a collar on the female luer fitting of the Rate-Control Set. If the wrong set is used, the syringe will be ejected from the Infuser. When the correct SIGMA 99400 Rate-Control Microbore Extension Set is used, it secures the syringe into the Infuser.

5) Only One Dose Can Be Administered Per Interval When Using The Multi-Doser - The mechanical lockouts prohibit unintentional overdose. The Multi-Doser products are designed to deliver fluids in 10cc dosing increments and the fluids are prepared in 10cc increments. When the user actuates the Multi-Doser to deliver 10cc, it is impossible to deliver more than one 10cc dose per interval. The dynamics of the syringe, Rate-Control Set, viscosity of fluid and the mechanical lockouts of the Infuser prevent the user from initiating more than one dose per interval.

6) Using Incorrect Drugs - The system is specified for non-rate critical drugs. The operator's manual and indications for use reflect this. Pharmacy labeling and hospital protocol for labeling are used for correct drug utilization, as with all medication systems in a hospital.

7) Incorrect Syringe Size - The Single-Doser Rev. I-10 will only accept a 10/12cc syringe and the Single-Doser Rev. I-20 will only accept a 20cc syringe. The Multi-Dosers are intended to be used with a 60cc syringe only. The labeling reflects that the Multi-Doser is to only be used with a 60cc syringe and the pharmacy will compound the intended drugs in 60cc syringes.

5.3
Conclusion of the Non-Clinical Testing Supporting Safety & Effectiveness
The system is intended for use with non-rate critical drugs and our specifications were established based on the intended use of the system. Our bench data proved that the system meets our specification and the design of the system lends itself to be used safely. In summary, the system meets the specification for its intended use and is found to be Safe and Effective.