



## 510(k) Summary

This summary regarding 510(k) safety and effectiveness and being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

### § 807.92 (a)(1) Submitter's (and Contact) Names, Address, Telephone No., Summary Date

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### § 807.92 (a)(2) Device Name (Including Trade Name), Common Name, Classification Name

- MX703/MX730
- Continuous flush device, fast flush
- Catheter, Continuous Flush (CV, 74 KRA)

### § 807.92 (a)(3) Legally Marketed Predicate Device to Which Equivalence is Claimed

- Medex, Inc.'s Microflush™ ( K770432).
- Sorenson Research Company, Inc. C.F.S. INTRAFLO® (pre-amendment)

### § 807.92 (a)(4) Description of the Premarket Notification Device

- The MX703 and the MX730 are 3cc/hr and 30cc/hr metering flushes, respectively. The MX703 3cc/hr flush has two (2) primary functions. First, it acts as a flow restrictor, allowing only a certain volume of flush solution to infuse per hour. This small hourly infused volume is necessary to maintain patency of a pressure line. The amount of volume infused per hour through the flush is maintained by pressure exerted on the flush solution by a pressure infusor. With the pressure gradient differences between the flush solution and the patient's physiological pressures, the volume of solution is infused through the flush and patency of the cannulated vasculature is maintained. The second function of the 3cc/hr flush is to give the clinician the ability to "fast flush". Fast flushes are necessary to clear the line following certain line manipulations (i.e. blood draws or medication administration).
- The MX730 30cc/hr flush has two (2) primary functions. First, it is used in pressure measurements which require continuous flow and the use of an infusion pump. The flush permits the fluid flow to be controlled by the infusion pump while it functions to isolate the pressure transducer from the pressure waveform noise generated by the pump. The 30cc/hr flow is great enough to allow the infusion pump complete control over the fluid flow while still restrictive enough to isolate the transducer from the noise generated by the pump during normal operation. Secondly, the MX730 is used to perform "fast flushes" under the same conditions and requirements as the MX703 above.



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- This MX703 and MX730 continuous flush devices and their intended use have been thoroughly reviewed against the ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" document per the blue book memorandum #G95-1. All materials have successfully met these standards.

### § 807.92 (a)(5) Intended Use

- The MX703/MX730 is an attachment to a catheter-transducer system that permits continuous intravascular flushing at a slow infusion rate for the purpose of eliminating clotting, back-leakage, and waveform damping

### § 807.92 (a)(6) Technical Characteristics Summary

<b>Property</b>	<b>Microflush™</b>	<b>MX703/MX730</b>	<b>Intraflo®</b>
Intended Use	The Microflush is an attachment to a catheter-transducer system that permits continuous intravascular flushing at a slow infusion rate for the purpose of eliminating clotting, back-leakage, and waveform damping.	The MX703/MX730 is an attachment to a catheter-transducer system that permits continuous intravascular flushing at a slow infusion rate for the purpose of eliminating clotting, back-leakage, and waveform damping.	The Intraflo is an attachment to a catheter-transducer system that permits continuous intravascular flushing at a slow infusion rate for the purpose of eliminating clotting, back-leakage, and waveform damping.
Biocompatibility	Unknown	ISO-10993	Unknown
Flow Restrictor Material	High density polyethylene (HDPE)	Silicone elastomer	Natural rubber
Method of Flush Actuation	Rotating plug	Push button	Pull tab
Momentary Flush Actuation	No	Yes	Yes
Flush Actuation	Two-hand operation	One hand operation	Two-hand operation
Nominal Metering Rate	3cc/hr	MX703 = 3cc/hr MX730 = 30cc/hr	3cc/hr
Operating Temperature	Unknown	+10° C to +45° C	Unknown
Clear Fluid Path	Yes	Yes	Yes
Vacuum Withstand	≤ -700mmHg	≤ -700mmHg	≤ -700mmHg
Fluid Path Configuration	Tortuous	Straight-through	Tortuous



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### § 807.92 (b)(1), (b)(3) Performance Testing Assessment

- The MX703/MX730 devices were aggressively tested for substantial equivalence to the two predicates (i.e. primary: Medex, Inc. Microflush; and secondary: Sorenson Research Co., Inc. C.F.S. Intraflo). Following a conditioning period (which included EtO sterilization, temperature cycling, and impact exposure), the units were tested under the following tests: vacuum, metering rate, flush rate, 40 psi withstand, and low pressure withstand tests. In all cases, the MX703/MX730 met or exceeded the performance of the predicates. The following table lists the test parameters and the respective performance of the MX703/MX730 (i.e. Button Flush), Microflush and the Intraflo.

TEST PARAMETER	SPECIFICATION	Button Flush N=40 99% Confidence t(.995,40)=2.704	MICROFLUSH N=10 99% Confidence t(.995,10)=3.169 - except as indicated for metering rates	INTRAFLO N=10 99% Confidence t(.995,10)=3.169 - except as indicated for metering rates
<b>1. Vacuum</b>				
# Leaks / Total	0 / Total	0/40	0/10	0/10
<b>2. Metering Rate - Adult (cc/hr) - 10°C</b>				
Mean (Approximate)	3.0 @ 15°C	2.34	t(.995,8)=3.355	2.25
Minimum (99% Lower Tail)	1.4 @ 15°C	1.61	1.51	1.46
Maximum (99% Upper Tail)	7.3 @ 15°C	3.07	4.19	3.04
Std. Dev.	-	0.27	0.4	0.25
<b>3. Metering Rate - Adult (cc/hr) - 45°C</b>				
Mean (Approximate)	3.0 @ 40°C	4.11	t(.995,7)=3.499	t(.995,9)=3.250
Minimum (99% Lower Tail)	1.4 @ 40°C	2.57	-0.56	2.88
Maximum (99% Upper Tail)	7.3 @ 40°C	5.65	8.76	4.98
Std. Dev.	-	0.57	1.47	0.33
<b>4. Metering Rate - Neonate (cc/hr) - 15°C</b>				
Mean (Approximate)	30.0 @ 15°C	22.83	N.A.	N.A.
Minimum (99% Lower Tail)	18.7 @ 15°C	18.07	N.A.	N.A.
Maximum (99% Upper Tail)	47.8 @ 15°C	27.59	N.A.	N.A.
Std. Dev.	-	1.76	N.A.	N.A.
<b>5. Metering Rate - Neonate (cc/hr) - 40°C</b>				
Mean (Approximate)	30.0 @ 40°C	34.64	N.A.	N.A.
Minimum (99% Lower Tail)	18.7 @ 40°C	27.83	N.A.	N.A.
Maximum (99% Upper Tail)	47.8 @ 40°C	41.45	N.A.	N.A.
Std. Dev.	-	2.52	N.A.	N.A.
<b>6. Flush Rate - Adult (cc/min) - 10°C</b>				
Mean (Approximate)	N.A.	110.64	327.73	121.25
Minimum (99% Lower Tail)	40.0	84.06	302.76	90.73
Maximum (99% Upper Tail)	N.A.	137.22	352.70	151.77
Std. Dev.	-	9.83	7.88	9.63
<b>7. Flush Rate - Adult (cc/min) - 45°C</b>				
Mean (Approximate)	N.A.	79.53	365.99	143.81
Minimum (99% Lower Tail)	40.0	51.95	331.73	98.97
Maximum (99% Upper Tail)	N.A.	107.11	400.25	188.65
Std. Dev.	-	10.20	10.81	14.15
<b>8. 40 Psi Withstand</b>				
# of Failed units	≥ 40 psi	0/40	0/10	0/10
<b>9. Low Pressure Withstand</b>				
# Bypassed below 15 psi	≥ 15 psi	0/40	0/10	0/10
<b>10. Vacuum Test - 720 mm Hg</b>				
# of Failed units	≤ -700 mm Hg	0/40	0/10	0/10