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K961404



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

- John Toomey
Senior Project Engineer
Medex, Inc.
6250 Shier-Rings Road
Dublin, Ohio 43017
(614) 791 5415
- 04.09.96

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

- MX960
- Reusable Pressure Transducer
- Transducer, Blood Pressure, Extravascular (CV, 74 DRS)

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

- Medex, Inc.'s MX860 NOVATRANS II[®] reusable pressure transducer (K951129).

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

- The MX960 reusable pressure transducer is a non-fluid pathway device. A pressure waveform is conveyed through a disposable dome which is coupled to the reusable pressure transducer during pressure monitoring. Both the transducer and dome have mutually exclusive diaphragms. Accordingly, fluid contact is limited to the dome portion of the system.
- The materials which comprise the MX960 have been aggressively tested per the ANSI/AAMI/ISO 10993 "Biological Evaluation of Medical Devices" and the "Tripartite Biocompatibility Guidance for Medical Devices". All materials have successfully met these standards.

§ 807.92 (a)(5) Intended Use

- The MX960 reusable pressure transducer is used to convert hemodynamic pressure waveforms via a piezoresistive bridge circuit into electrical signals which can then be displayed using separate monitoring equipment.



§ 807.92 (a)(6) Technical Characteristics Summary

Property	Predicate MX860	MX960
Intended Use	The MX860 reusable pressure transducer's intended use is to convert hemodynamic pressure waveforms via a piezoresistive bridge circuit into electrical signals which can then be displayed using separate monitoring equipment.	The MX960 reusable pressure transducer's intended use is to convert hemodynamic pressure waveforms via a piezoresistive bridge circuit into electrical signals which can then be displayed using separate monitoring equipment.
Pressure Sensing Component	Piezoresistive Wheatstone bridge network	Piezoresistive Wheatstone bridge network
Balanced Fluid Path	Yes	Yes
Performance Specifications	Meets or exceeds ANSI/AAMI BP22-1994	Meets or exceeds ANSI/AAMI BP22-1994
Construction Material	Polycarbonate	Polycarbonate
Height - Maximum Dimension	0.657"	0.657"

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

- The MX960 was aggressively tested against the American National Standard for Blood Pressure Transducers, ANSI/AAMI BP22-1994. In all cases, the MX960 meets or exceeds AAMI specifications. The following table list the AAMI requirements, and the respective performance of the MX860 and the MX960.

PARAMETER	PREDICATE MX860	MX960	AAMI SPECIFICATION
Sensitivity - $\mu V/V/mmHg$	5.0 Nominal	5.0 Nominal	Disclosure
Unbalance - mmHg	0 ± 50	0 ± 50	0 ± 75
Zero Drift - mmHg	≤ 2 in 4 hrs after 5 min	≤ 2 in 4 hrs after 5 min	Disclosure
Input Impedance - OHMS	630 Nominal	630 Nominal	< 3000
Output Impedance - OHMS	$300 \pm 10\%$	$300 \pm 10\%$	> 200
Calibration Requirement - mmHg	100 ± 3	100 ± 3	Not Specified
Accuracy - mmHg	meets or exceeds AAMI	meets or exceeds AAMI	$< \pm 1 \pm 1\%$ or $< \pm 3\%$
Compensated Temperature Range - $^{\circ}C$	10 to 45	15 to 40	15 to 40
Storage Temperature Range - $^{\circ}C$	25 to 70	-25 to 70	-25 to 70
Temperature Coefficient of Sensitivity - $\%/C^{\circ}$	0 ± 0.1	0 ± 0.1	Disclosure
Temperature Coefficient of Offset - $mmHg/C^{\circ}$	0 ± 0.3	0 ± 0.3	Disclosure
Operating Pressure - mmHg	30 to 300	30 to 300	-30 to 300
Overpressure - mmHg	-700 to 4000	-400 to 4000	-400 to 4000
Volumetric Displacement - $\mu L/100mmHg$	Not Specified	Not Specified	Not Specified
Symmetry -	$1 \pm 5\%$	$1 \pm 5\%$	$1 \pm 5\%$
Defibrillator Withstand - per AAMI	5 in 5 min at 360J	5 in 5 min at 360J	5 in 5 min at 360J
Leakage Current of 115 VAC at 60 Hz - μA	< 3	< 5	< 10
Light Sensitivity - per AAMI	$< 1mmHg$ shift	$< 1mmHg$ shift	Disclosure
Mechanical Shock Withstand - per AAMI	3 falls from 1m	3 falls from 1m	Disclosure
Phase Shift - per AAMI	$< 5^{\circ}$	$< 5^{\circ}$	$< 5^{\circ}$